Inspection Policy on Announced/Unannounced Inspections

January 2014

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Executive Summary

The Pharmaceutical Society of Ireland (PSI) is an independent statutory body, established by the Pharmacy Act 2007. It is charged with, and is accountable for, the effective regulation of the pharmacy profession and the operation of pharmacies in the state to protect the health and safety of the public. The PSI is expected to assure the public that pharmacy services are delivered in a competent professional and ethical manner and in an appropriate environment, to the highest standards of quality care and best practice. The PSI is responsible, inter alia, for supervising compliance with the Pharmacy Act 2007 and the instruments made under it. In the discharge of these functions, the PSI conducts compliance inspections, under part 7 of the Pharmacy Act 2007, to:

- To monitor and assess compliance with pharmacy and medicines legislation and PSI Guidelines.
- Provide assurance to the public that the regulatory system for pharmacists and pharmacies is robust and acts in the best interests of patients and the public.

Compliance inspections are carried out on an 'unannounced' basis[1]. The average compliance inspection last approximately two hours. Inspectors review a number of legal records including registers and prescriptions. Under law these records must be present at the pharmacy and demonstrate accountability for the safe management and custody of medicines. Inspectors also review hygiene and medicines storage standards at the premises. Specific pharmacy personnel e.g. Superintendent, Supervising Pharmacist or Managers are not required to be present for a pharmacy compliance inspection. The observations made at inspection and any follow up required actions are communicated in a report which issues after the inspection. Overall, the current purpose of compliance inspection is to assess how a pharmacy operates on any particular day.

The Inspection and Enforcement Committee of the Council of the PSI requested a review of PSI policy in respect of the conduct of 'unannounced' compliance inspections[2]. The basis for the proposal is to provide pharmacy owners and Superintendent Pharmacists with short advance notice that an inspection will be carried out (typically one working day), so that they may review staffing arrangements at the pharmacy for the day of the inspection and to provide them with the opportunity to ensure that key personnel are present. In view of the fact that this proposal would constitute a significant change in existing policy, the Committee requested the completion of a report:

i. To examine national and international best practice for compliance inspections
ii. To conduct a pilot of announced compliance inspections and report on
    - any material differences noted between the outcomes of announced and unannounced inspection, and
    - any advantages or disadvantages noted between announced and unannounced inspections, including a review of costs and resources.
iii. To consult with key national stakeholders on announced and unannounced pharmacy inspection policy

The PSI reviewed international pharmacy regulatory practices regarding the conduct of announced and unannounced inspections[3]. The significant majority (eight of the nine) of international pharmacy regulators[4], who provided information to the PSI favoured either:

(a) The conduct of unannounced compliance inspections (five regulators[5]); or

[1] The inspected party is not notified in advance of these inspections.
[2] For cause compliance inspections (i.e. investigations) are excluded from this review.
[3] A selection of international pharmacy regulators were contacted for information on their inspection policies using Survey Monkey and/or via telephone or email. Published information on the various regulatory authorities' policies was also relied on for the purposes of the review.
[4] Reference Part A of the report: International Pharmacy Regulators and Inspection Policies
[5] The regulator in Northern Ireland, three Australian regulators and one Canadian regulator

(b) The conduct of announced inspections in circumstances where pharmacies are put on notice that they will be inspected within a given time period (three regulators[6]). The exact date of the inspection is not notified in advance.

Two of the regulators inform pharmacists they will be inspected within a six month time period. The third regulator, the GPhC (UK) which uses notification periods is rolling a new inspection format and is currently notifying most, but not all, compliance inspections, informing pharmacies that they will be inspected within a two week period (four to six weeks in advance). This regulator, the GPhC in the UK, have informed the PSI they intend to move an entirely unannounced inspection format.

It was suggested by a majority of the regulators that unannounced inspection models/non-specifc date notification periods provide a true and accurate representation of the manner in which the pharmacy is operated on a day to day basis and that unannounced inspections were often the preference of patients and/or the government. All of the international regulators agreed that unannounced inspections are appropriate where there are concerns in relation to a pharmacy's practice, following a complaint, where criminal activity is suspected and when they are re-inspecting due to previously identified deficiencies.

The PSI reviewed national practices by other regulators in regard to the conduct of announced and unannounced inspections. The findings show that other national healthcare regulators/agencies generally support the use of 'unannounced' inspection models for compliance inspections because they represent a clearer insight into the reality of the service as experienced by residents/patients and to prevent practices from being visibly altered. Announced inspections tend to be favoured in pharmaceutical industry to ensure that relevant personnel are present, site visits can be conducted and that certain documentation is available for review. However, it was noted that there are significant differences between the inspection of pharmacy services and pharmaceutical industry and wholesaling settings due to the comparative size of pharmaceutical manufacturing/wholesaling facilities, the complexity of the activities carried out and the usual duration of the inspection (e.g. a number of days).

A pilot study was carried out to investigate whether the provision of 24 hours advance notice of inspections would impact the outcomes observed at inspection[7]. Marginal differences were noted between inspection outcomes from the announced and unannounced inspections. Improvements in the completion of the duty register, error records and labelling of medicines which had been removed from their primary packaging were noted at announced inspections. Few pharmacies availed of the 24 hour notice period to change staffing arrangements at the pharmacy for the purposes of the inspection.

The PSI reviewed the resource implications associated with the conduct of an unannounced inspection regime. The PSI carried out an analysis of the resources required to conduct a sample month of unannounced inspections in 2013 and the projected resources which would be required to conduct the same sample month of inspections on an announced basis. The findings indicate that an announced inspection policy is expected to result in an increase in costs to the organisation due to increased administration, travel and subsistence expenditure and travel time. The increased costs and increased demand on inspectors' time is also relevant in considering the objectives sought from an announced inspection policy.

The PSI engaged in a targeted consultation with a number of key stakeholders in relation to the proposed change in PSI inspection policy. The majority of respondents strongly favoured the conduct of unannounced inspections because they are perceived to provide a better insight into the actual level of care delivered to

[6] The UK regulator, one Canadian regulator and one Australian regulator. The Australian and Canadian regulator utilised 6 month notification periods.

[7] The study comprised the comparison of average non-compliant outcomes from inspections carried out in 2013 with outcomes resulting from a pilot of 40 announced inspections which were carried out in 2014

patients or residents[8]. Respondents indicated that a combination of announced and unannounced inspections may be appropriate in certain limited circumstances i.e. following the successful completion of unannounced inspections; in circumstances where there is supporting criteria e.g. clear previous audit.[9] One stakeholder welcomed the proposal of announced inspections stating that the current unannounced inspection model poses a risk to patient safety as a pharmacist's attention is drawn away from professional duties.[10] The Department of Health expressed the view that patient safety and public protection was best regulated within the confines of unannounced inspections.

Conclusion and Recommendations

The evidence shows that the current inspection policy, whereby compliance inspections are not announced to inspected parties in advance, is generally consistent with national inspection practices, international pharmacy inspection practices and stakeholder opinion. The PSIs current inspection policy is also consistent with the policy of the Department of Health, with whom the PSI have a direct reporting relationship.

The first inspection cycle of all pharmacy inspections in the State is due for completion by year end 2014, at which point the PSI will have, for the first time under the Pharmacy Act 2007, established a compliance baseline. Having established that baseline, this information will be used to refine and develop the inspection and enforcement policy for the period 2015-17. In the context of future strategy, the PSI is committed to considering the feasibility of all compliance tools and potential approaches which may be appropriate to assure patient safety and which can efficiently achieve the best compliance standards in the pharmacy sector. This may include the potential use of self-assessment, risk based approaches to inspection, a change to practice focused inspections, and/or Superintendent Pharmacist led self-audit. There may also be circumstances where the utilisation of announced compliance inspections may be appropriate e.g. in cases of good and consistent audit history etc.

However, until such time as the inspection strategy is further informed or defined, and/or greater information from tools such as self-assessment or future inspection cycles has been gathered, the Executive would caution against any commitment to an announced inspection policy for compliance inspections.

The Executive of the PSI recommends the following:

1. To continue to develop a quality and risk system for inspecting pharmacies in collaboration with stakeholders:
   - in line with evolving good regulatory practices and the needs of patients and the pharmacy sector
   - having regard to the various inspection tools/and baseline information available.

2. To consider the potential for the use of announced compliance inspections as part of an overall strategic review of inspection policy during 2015 and in response to improving compliance standards and audit practices within the pharmacy sector.

3. To maintain the current unannounced inspection policy, in keeping with the existing PSI Corporate Strategy and international and national practices.

[8] Irish Patients Association, Patient Focus, Metal Health Commission
[9] Irish Patients Association, Patient Focus, Mental Health Commission, HIQA,
[10] Irish Pharmacy Union

Introduction

The Pharmaceutical Society of Ireland

The Pharmaceutical Society of Ireland (PSI) is an independent statutory body, established by the Pharmacy Act 2007. It is charged with, and is accountable for, the effective regulation of the pharmacy profession and the operation of pharmacies in the state to protect the health and safety of the public. The PSI aims to ensure that pharmacy services are delivered in a competent professional and ethical manner and in an appropriate environment, to the highest standards of quality care and best practice. Under the Pharmacy Act 2007, the PSI is responsible, inter alia, for supervising compliance with the Act and the instruments made under it.

In the discharge of these functions, under Part 7 of The Pharmacy Act 2007, the PSI conducts inspections of pharmacies. The PSI's inspection policy is informed by our core remit of protecting patient safety and public health. The PSI carries out two types of inspections (i) registration related inspections and (ii) non-registration related or "compliance inspections". Inspected parties are notified in advance of registration related inspections (announced inspections). Inspected parties are not notified in advance of compliance inspections (unannounced inspections).

Proposal to Review Inspection Policy: Inspection & Enforcement Committee

The Inspection and Enforcement Committee of the Council of the PSI requested a review of PSI policy in respect of the conduct of compliance inspections[5] which to date have been generally operated on an 'unannounced' basis[6]. The basis for the proposal is to provide pharmacy owners and Superintendent Pharmacists short advance notice that an inspection will be carried out (typically one working day), so that they may review staffing arrangements at the pharmacy for the day of the inspection and to provide them the opportunity to ensure that key personnel are present.

In view of the fact that this proposal would constitute a significant change in current policy, the Inspection and Enforcement Committee has sought a report to be completed on the matter. In particular, the Committee agreed that the following themes should be addressed in the report:

i. Examine national and international best practice for inspections
ii. Consult with key national stakeholders on announced and unannounced pharmacy inspection policy
iii. Conduct a pilot of announced compliance inspections and report on
    - any material differences noted between the outcomes of announced and unannounced inspection, and
    - any advantages or disadvantages noted between announced and unannounced inspections, including a review of costs and resources.

The Inspection and Enforcement Unit of the PSI completed a report accordingly, as set out hereunder:

Section 1: Background
Section 2: Inspection Policy: A Review Of National And International Regulators/Inspection Agencies
Part A: International Pharmacy Regulators and Inspection Policies
Part B: National Regulators/Inspection Agencies and Inspection Policy

[5] For cause compliance inspections (i.e. investigations) are excluded from this review.
[6] Inspection & Enforcement Committee of the PSI Meeting 19/11/2013.

Section 1: Background

1.1 Principles of Regulation

Regulation may be referred to as sustained and focused control exercised by a public agency/body over activities that are valued by a community, and in healthcare specifically as any set of influences or rules exterior to the practice of administration of medical care that imposes rules or behaviour[7].

Regulation is designed to serve three objectives:

- To improve performance and quality
- To provide assurance that core standards are achieved
- To provide accountability both for levels of performance and value for money[8]

Inspection can be defined as a mechanism of 'external oversight' where experts make periodic visits to a regulated organisation in order to assess its performance and accreditation [registration] status[9].

1.2 PSI Corporate Strategy 2013-17

The PSI, as the Pharmacy Regulator, acts to protect and promote the health and safety and well-being of patients and the public. It aims to ensure that pharmacy services are delivered in a competent, professional and ethical manner and in an appropriate environment, to the highest standards of quality care and best practice, and well-being of patients and the public[10].

The PSI is obligated under Statute to inspect retail pharmacy businesses to assess compliance with the Pharmacy Act 2007 and with other pharmacy and medicines legislation and guidelines. The purpose of the inspection function is to promote good and safe pharmacy practice within retail pharmacy businesses. Under the Corporate Strategy, the PSI is committed to the delivery of an effective compliance system.

The PSI has set out the following objectives for delivering an effective compliance system in its Corporate Strategy 2013-17:

- By mid-2015, every community pharmacy will have received one formal inspection
- During the period 2013-15, the PSI will continue to refine and develop the system of inspection and enforcement across all types of pharmacy
- During the period 2015-17, the PSI will develop its quality and risk system for inspecting pharmacies
- The PSI will consider the feasibility of introducing a self-assessment for pharmacies, as part of the wider quality and risk based inspection.

1.3 PSI Inspections

The PSI carries out both announced and unannounced inspections. Registration related inspections are always announced and non-registration related inspections are unannounced.

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[7] *Building a Culture of Patient Safety*, Report of the Commission on Patient Safety and Quality Assurance, July 2008, pp.107

[8] Regulation and quality improvement . A review of the evidence. Sutherland and Leatherman 2006b, London, The Health Foundation

[9] *Building a Culture of Patient Safety*, Report of the Commission on Patient Safety and Quality Assurance, July 2008, pp.107.

[10] PSI Corporate Strategy 2013-2017, Mission Vision and Values of the PSI

Registration Related Inspections

Where the PSI conducts an inspection on foot of an application to register[11] or to continue to register a retail pharmacy business, the PSI gives notice of the inspection in writing to the applicant.[12] This inspection assesses compliance with the Regulation of Retail Pharmacy Businesses Regulations 2008 and PSI Guidelines. The purpose of the notification is to ensure that the proposed pharmacy premises (which is not ordinarily open to the public) is accessible for inspection and that the relevant personnel are present.

Non- Registration Related Inspections (Compliance Inspections)

The PSI carries out compliance inspections of retail pharmacy businesses to assess compliance with the Pharmacy Act 2007 and with other pharmacy and medicines legislation and guidelines. The primary objective of compliance inspections is to promote and ensure high standards of compliance with legislative requirements, guidelines, best practice requirements and the Code of Conduct for Pharmacists and to assure the safe delivery of pharmacy services in the public interest.

The average compliance inspection last approximately two hours. As part of a compliance inspection, inspectors review a number of legal records including registers and prescriptions. Under law these records must be present at the pharmacy and readily to hand. These records demonstrate accountability for the safe management and custody of medicines. Inspectors also review hygiene and medicines storage standards at the premises. Specific pharmacy personnel e.g. Superintendent, Supervising Pharmacist or Managers are not required to be present for a pharmacy compliance inspection. The observations made at inspection and any follow up required actions are communicated in a report which issues after the inspection.

In the interests of transparency and in order to facilitate compliance, the PSI has published a checklist and a podcast to assist pharmacy owners and pharmacists to prepare for compliance inspections. The checklist and podcast are available at www.thepsi.ie. The Inspection and Enforcement Unit also issue updates in the PSI newsletters to assist pharmacists in the inspection process.

As part of the PSI's Corporate Strategy, the Inspection and Enforcement Unit of the PSI is committed to completing the inspection of every pharmacy in the State by mid-2015. All pharmacy compliance inspections in the current inspection cycle have been carried out on an unannounced basis, with the exception of those inspections which were announced as part of the pilot study outlined in Section 3 of this report.

The information obtained following the completion of the 2014 pharmacy inspection cycle will inform risk based and strategic planning for future pharmacy inspection cycles. The information also informs the PSI Practice of Pharmacy Development Unit and the targeted development of PSI Guidelines.

[11] Section 19 of the Pharmacy Act 2007 provides that in any case where the Council considers it appropriate, it may cause an authorised officer to inspect the premises of a retail pharmacy business in respect of which an application for registration or continued registration has been made to ascertain if they comply with any regulations made by the Minister under section 18.

[12] Rule 5 (2)(c) of the Pharmaceutical Society of Ireland (Retail Pharmacy Businesses)(Registration)Rules 2008

Section 2: Inspection Policy Review of National & International Regulators/Inspection Agencies

Part A International Pharmacy Regulators and Inspection Policies

Part B National Regulators and Inspection Policy

Part C PSI Questionnaire on Inspection Policy

Part A: International Pharmacy Regulators and Inspection Policies

To obtain information on international regulatory practices with regard to pharmacy inspections, a selection of international pharmacy regulators were contacted for information on their inspection policies[13]. This information was supported by published information on the various regulatory authorities' policies. The review of their inspection policies focused on the use of announced and unannounced inspections.

Responses and information on inspection policy was received from the following regulatory bodies:

- The General Pharmaceutical Council (GPhC), United Kingdom
- The Department of Health, Social Services and Public Safety (DHSSPS), Northern Ireland
- The Pharmacy Registration Board of Western Australia
- The Pharmacy Council of New South Wales, Australia
- The Pharmacy Regulation Authority, South Australia
- The Tasmanian Pharmacy Authority, Australia
- Health Care Inspectorate, Ministry of Health, the Netherlands
- The Ontario College of Pharmacists, Canada
- The Alberta College of Pharmacists, Canada

The findings are summarised below:

2.1 The General Pharmaceutical Council (GPhC), United Kingdom

The General Pharmaceutical Council (GPhC) is the independent regulator for pharmacists, pharmacy technicians and pharmacy premises in Great Britain. Their core role is to protect, promote and maintain the health, safety and wellbeing of members of the public by upholding standards and public trust in pharmacy. The GPhC currently inspect registered pharmacies approximately once every three years.

From November 2013, the GPhC rolled out a prototype of a new inspection approach utilislising a combination of announced and unannounced inspections. As part of this new approach to inspections, they are moving to an increasingly risk-based approach where pharmacies which pose **greater** concerns for patient safety are inspected more frequently.

Most inspections during the prototype phase are announced. The GPhC notify pharmacies that an inspection will take place four to six weeks in advance of the inspection, but they do not inform the pharmacy of the date or time of the inspection nor do they require specific persons to be present. They have stated that they notify pharmacies primarily to raise awareness of their new inspection model and of the standards they expect pharmacies to meet. Their inspection aim, insofar as is possible, is to replicate the experience of a patient who

[13] Via a Survey Monkey Questionnaire and/or via telephone or email.

attends at a pharmacy. Their expectations are that a pharmacy should meet the standards every day and they therefore don't believe they should notify a specific date of inspection.

The GPhC are also undertaking testing on the use of unannounced inspections during the prototype phase. Their early testing has indicated that there is no impact on the outcome of an inspection if it is unannounced.

The GPhC also conduct unannounced inspections when they receive information that a pharmacy may be a risk to patient safety.

Through consultation with patients and the public, the GPhC state it is clear that the public feel inspections should be unannounced as this is how patients and the public experience pharmacies on a day to day basis. The GPhC have stated that they intend to ultimately move to a position of entirely unannounced inspections.[14]

2.2 The Department of Health, Social Services and Public Safety (DHSSPS), Northern Ireland

The Medicines Regulatory Group (MRG) within the Department of Health, Social Services and Public Safety (DHSSPS) is the entity responsible for inspection and enforcement under all medicines related legislation in Northern Ireland. They inspect many pharmaceutical and healthcare areas, ranging from pharmaceutical manufacturers to hospitals and medical practices. Their responsibilities include the inspection of community pharmacies. To this end, they work closely with the Pharmaceutical Society Northern Ireland (PSNI) and can gather information, conduct investigations, inspect premises and take statements on their behalf. The DHSSPS inspect new pharmacy premises and these inspections are carried out on an announced basis.

They have indicated that they achieve compliance in community pharmacies through a system of unannounced inspections, follow-up visits and investigation and enforcement activities. They received soundings several years ago, which included feedback from the PSNI's Law and Ethics committee, which indicated that the preference was for unannounced compliance inspections. They believe that unannounced inspections give a more realistic snapshot of how a pharmacy is operating.[15]

2.3 The Pharmacy Board of Australia and their Eight Regional Boards

The Pharmacy Board of Australia works in partnership with the Australian Healthcare Regulation Practitioner Agency to protect the public and guide the pharmacy profession and its responsibilities include registering pharmacists, managing complaints and developing standards.

Various state pharmacy boards, councils or pharmacy authorities have pharmacy inspection and other pharmacy regulation responsibilities. Australia has eight regional boards.[16]

The PSI received information on the inspection process in four Australian States as set out below:

- The Pharmacy Registration Board of Western Australia
- The Pharmacy Council of New South Wales
- The Pharmacy Regulation Authority, South Australia
- The Tasmanian Pharmacy Authority

[14] Questionnaire response and GPhC website: http://pharmacyregulation.org/.
[15] Questionnaire response, telephone conversation with DHSSPS MRG inspection staff and DHSSPS website: http://www.dhsspsni.gov.uk.
[16] Pharmacy Board of Australia Website: http://www.pharmacyboard.gov.au.

Three of these four Australian states carry out unannounced routine compliance inspections. The fourth state informs pharmacies that they will be inspected within a particular six month time period for most routine compliance inspections. Further detail is set out below:

A. The Pharmacy Registration Board of Western Australia

The Pharmacy Registration Board of Western Australia only conduct unannounced inspections. Their rationale for conducting unannounced inspections is to ensure pharmacies are compliant at all times rather than just when notified that an inspection will be occurring. They believe this helps develop a culture of ongoing compliance.[17]

B. The Pharmacy Council of New South Wales

The Pharmacy Council of New South Wales (NSW) conduct a mixture of announced and unannounced inspections. Announced inspections are conducted in respect of new pharmacy openings, relocations or the resizing of existing pharmacy premises.

Routine inspections of pharmacies are conducted once every eighteen months and unannounced inspections are used in this context. Follow up inspections and inspections in relation to complaints are also unannounced. The Council feels that there is no need to give advance notice for routine inspections.[18]

C. The Pharmacy Regulation Authority, South Australia

In South Australia compliance inspections are conducted on a random basis across a three year period to ascertain the level of adherence to published standards and guidelines. These inspections are announced, insofar as pharmacies are notified that they may be inspected anytime within a six month period. The exact time or date of the inspection is not notified in advance. The Authority provides this level of notification to enhance co-operation between the regulatory authority and pharmacists and pharmacy owners and to endeavor to ensure the maintenance of the highest level of standards. They feel notification lends itself to the spirit of cooperation at the initial stages of the process and provides an opportunity for any premises that has allowed the standards to slip to review and improve their standards prior to the inspection. They also feel it allows time for reflection in advance of the visit and reduces the adversarial context of the inspection.

Depending on the level of remedial action required, the Authority may elect to re-inspect a pharmacy. Unannounced inspections are used in this context. They also conduct unannounced inspections where they have received information in relation to the practices at a pharmacy. The Council employ unannounced inspections to ensure they are inspecting a true reflection of the practices at a pharmacy and to ensure that where there have been previous commitments to improvement that there has been actual rather that suggested improvement.[19]

D. The Tasmanian Pharmacy Authority

In Tasmania inspections are only announced for new pharmacy registrations or where there are alterations to a pharmacy premises. These inspections are notified so that the pharmacist in charge and/or the owners can be present and can immediately rectify issues and so that the regulator can discuss and educate those in charge about relevant standards.

Routine pharmacy compliance inspections are conducted on a three year basis and are generally unannounced. The aim of these inspections is, in the main, to improve standards. They also conduct unannounced inspections if potential non-compliances have been brought to their attention or if previous

[17] Questionnaire response
[18] Questionnaire response
[19] Questionnaire response

inspections identified serious issues. They perceive that unannounced inspections are advantageous because they don't allow the inspected party to hide or destroy evidence when there is an intentional practice breach. In addition, where issues have been highlighted at a previous inspection they believe it allows a more accurate assessment of whether or not these issues had been adequately addressed.[20]

2.4 Health Care Inspectorate, Ministry of Health, the Netherlands

The Health Care Inspectorate inspects healthcare professionals acting in prescribing, dispensing and administration of medicine roles, including hospital and community pharmacists and provides oversight in the area of public health.

The Inspectorate conducts a mixture of announced and unannounced inspections. They utilise announced inspections to determine compliance with the law and if there are risks to patients where there is no previous evidence of avoidance or malpractice. They provide notification periods of between two and six weeks. The perceived benefits of announcing inspections are to ensure key personnel, e.g. the responsible pharmacist is available for the inspection and to prevent inefficiencies. They perceive that where preparation or cover up before an inspection occurs that this is usually easily recognisable by well trained and educated inspectors. Their inspections usually take approximately half a day or four hours.

The Inspectorate sometimes conduct announced inspections with 24 hours' notice. This notification is provided to enable important personnel to be available during the inspection. This compromise occurred to increase the trust of the general public in the objective results of the inspection, while also allowing a level of preplanning.

The Inspectorate also conduct unannounced inspections where they have received information that is of concern from two or more sources, where previous non-compliances have been identified or where criminal offences are suspected. One of their motivations for carrying out unannounced inspections is the opinion of the government that most, if not all, inspections should be unannounced.[21]

2.5 National Association of Pharmacy Regulatory Authorities (NAPRA), Canada and their Thirteen Provincial/ Territorial Licensing Bodies.

The NAPRA is a voluntary association of the provincial and territorial pharmacy regulatory bodies in Canada. The provincial bodies regulate the practice of pharmacy and operation of pharmacies in their respective jurisdictions and their primary mandate is to protect the public. Pharmacy regulators across Canada have both the right and responsibility to inspect pharmacies. Canada has thirteen provincial regulatory bodies.[22]

The PSI received information on the inspection process from two of these regulatory bodies:

- The Ontario College of Pharmacists
- The Alberta College of Pharmacists.

Both Canadian states carry out unannounced routine or compliance inspections. However, in Ontario they inform most pharmacies that they will be inspected within a certain six month time period for most routine compliance inspections. Further detail is set out below:

A. The Ontario College of Pharmacists

[20] Questionnaire response
[21] Questionnaire response
[22] NAPRA, Canada website: http://napra.ca/pages/home/default.aspx

In Ontario, every licensed pharmacy is routinely inspected once every three to five years. Previously they conducted only unannounced inspections. However, more recently they have engaged with the profession outlining what the standards expected are and moved the focus from just the physical equipment/ premises and prescription and narcotic checks (which are still inspected) to best practice expectations. Partial notification now occurs for routine compliance inspections. Fully announced inspections only occur for new pharmacy openings.

For routine compliance inspections, the pharmacy is informed that an inspection will occur in the next six months and is invited to inform them if specific days of the week are more suitable or if the main pharmacist will be on vacation certain dates. No specific date or time for the inspection is arranged. They believe this notification provides an opportunity for pharmacists to review the operation of the pharmacy and allows the pharmacist to highlight anything they wish to discuss with the inspector during the visit. Specific inspection appointments are not made primarily for logistical reasons. Routine inspections in Ontario typically last for three to six hours. The Ontario College of Pharmacists have indicated that they will be reassessing their need to make appointments with a move to more practice based inspections as specific and adequate staff may need to be present for the inspection.

They have different levels of inspections, with routine inspections falling into the above description. Where previous deficiencies have been identified the inspection level is elevated and parties are not notified of the inspection. Where serious issues are repeatedly not addressed, the inspection costs are borne by the inspected party.[23]

B. The Alberta College of Pharmacists

In Alberta all pharmacy inspections are unannounced. Their rationale is that this allows them to inspect pharmacies in their natural state rather than after an artificial cleanup operation. It also allows the College to set realistic expectations for the pharmacy. Another reason inspections are unannounced is to allow the inspectors to manage their inspection schedule in more efficient manner.[24]

A table summarising the findings of the review is included at Appendix 1.

Part B: National Regulators/Inspection Agencies and Inspection Policy

In order to obtain information on national regulatory practices with regard to announced and unannounced inspections, a selection of national healthcare regulatory bodies were contacted for information on their inspection policies[25]. The purpose of the review was to gain an understanding of the inspection approaches adopted by the various regulators and the reasons for operating announced and/or unannounced inspections policies. Supporting information was obtained from published information on the various regulatory bodies' policies[26].

The practices of the following regulators were reviewed:

1. The Health Information and Quality Authority (HIQA) Residential Services for Older and Dependent People and for People with Disabilities
2. The Mental Health Commission (MHC)

[23] Questionnaire response and email correspondence from the former Registrar of the Ontario College of Pharmacists
[24] Questionnaire response
[25] See PSI Questionnaire Section 2 Part C of this report.
[26] Websites, Policy Documents, Phone call

3. Irish Medicines Board (IMB)
4. Departure of Agriculture, Food and Marine

2.6 HIQA – Residential Services for Older and Dependent People and for People with Disabilities

The Health Information and Quality Authority (HIQA) is responsible under law, for regulating the quality of services provided in designated centres for older and dependent people, children and adults with disabilities. HIQA registers and inspects residential services in order to protect vulnerable people of all ages who are receiving residential care services and to ensure that these people are receiving an appropriate standard and quality of service.

The purpose of HIQA inspections is to monitor compliance with appropriate regulations and standards, to report on the quality of service and to gather evidence on which to make judgements on the fitness of registered providers.

HIQA carries out a number of different types of inspection:

a) **Registration Related Inspections**
Registration related inspections are always announced. This is to ensure that relevant personnel and records are available and to facilitate residents and relatives interacting with inspection staff if they wish.

b) **Non-registration Related Inspections**
Non-registration related inspections tend to be unannounced in the main, though HIQA have indicated that they have started to use announced inspections in an attempt to place increasing emphasis on the objective of driving improvement as well as monitoring compliance with standard and guidelines. Inspections and follow up inspections are informed by the provider's level of compliance with standards and regulations determined on previous inspections. The purpose of these inspections is to ensure critical elements of care and support are in place, including staffing on a 24/7 basis. These inspections are also carried out to follow up on previous inspection findings/commitments by providers and ensure actions have been taken as promised. Unannounced inspections are used by HIQA to ensure that the reality of the service as experienced by residents is assessed, with no scope for manipulation of that reality by other parties[27].

c) **Investigation**
Both announced and unannounced inspections are used in the course of an investigation where there is concern for patient safety and welfare or where it is believed there is emergent or actual risk.

2.7 Mental Health Commission Ireland (MHC)

The Mental Health Commission is an independent statutory body established under the Mental Health Act 2001. The Mental Health Commission maintains a register of approved centres (inpatient psychiatric units) for the care and treatment of persons suffering from mental illness or mental disorders. It is responsible for ensuring that the interests of those involuntarily admitted to approved centres are protected and for promoting high standards in the delivery of mental health services.

[27] Reference Survey Comments –Deputy Director of Regulation (Adult Social Care)

(a) The Mental Health Inspectorate conducts inspections of approved centres to monitor and assess the compliance of mental health services with the 2001 Act, Rules and Codes of Practice. These statutory inspections are unannounced and typically last for 1-2 days. This policy position is based on a desire to be able to review services as they exist and which are not presented as a showpiece[28].

(b) The Mental Health Commission also carries out announced inspections which they also refer to as 'catchment area meetings' or 'national area meetings'. The purpose of these inspections or meetings is to ascertain a broad overview of mental health services in a particular catchment area or nationally. They are notified in advanced in order to make sure certain relevant personnel are in attendance to discuss aspects of the mental health service in particular geographical areas.

2.8 Irish Medicines Board (IMB)

The Irish Medicines Board is responsible for regulating medicines, medical devices and healthcare products as well as cosmetic products in Ireland. The IMB is also the Competent Authority for the implementation of EU and national legislation relating to blood and blood components, organ transplantation and also for tissues & cells[29]. The IMB monitors the quality of medicines and medical devices by conducting inspections at sites of manufacture and distribution of medicines and by random sampling of products both pre and post authorisation. While this agency has been selected for review in the context of announced and unannounced inspections because it deals with the regulation of medicinal products in a national context, it should be noted that the regulation of medicines is a multi-stage process, which is closely monitored and inspected from the first application to the market, throughout manufacture, production and labelling, storage and distribution. To this end, there are significant differences between the inspection requirements for pharmaceutical industry and the delivery of pharmacy services which is subject to a single inspection.

The IMB carries out inspections of, inter alia, the following[30]:

- Manufacturers and wholesalers of medicinal products (Human and Veterinary)
- Marketing Authorisation Holders

The purpose of these inspections is to check compliance with licensing conditions and/or approvals granted against applicable standards.

(a) The vast majority of the inspections carried out at manufacturing and wholesaling facilities by the IMB are announced. These Inspections often require:
    - Pre-inspection opening meeting with designated personnel.
    - Specific persons to be present e.g. the qualified person (QP).
    - Site/facility tours - which need to take account of health and safety considerations.
    - The inspection to be coordinated with site validation schedule in order to accurately assess facilities' processes and equipment
    - The inspected party to have an area designated for paperwork review.
    - Closing meeting with management and key personnel to set out a summary of findings and possible corrective/preventative actions.

    These inspections are announced 6 weeks in advance of the inspection date. It is submitted that this facilitates the best use of time on site and it allows for the preparation of documents which need to be presented on the first day of the inspection. In addition, notification is considered necessary to

[28] Reference Survey Comments –Inspectorate of Mental Health Services

[29] http://www.imb.ie/EN/About-Us.aspx

[30] This is not an exhaustive list. Inspections relating to medicines will be relied on for the purposes of this review

ensure that there is no clash between inspections being performed by other agencies. In the case of inspections of facilities outside the state, a letter of invitation from the company is often required to process visa applications and so these inspections must be announced.

(b) The IMB also carry out unannounced inspections to check the compliance status of a site or company. Unannounced inspections may be conducted where there is a suspected breach of good practice and where there is a likelihood that the evidence would be removed if it was known that an inspection was to take place.

(c) The IMB also carry out inspections of pharmacies under Section 32 of The Irish Medicines Board Act 1995 (as amended). These inspections review traceability requirements for medicines and are unannounced.

2.9 Departure of Agriculture, Food and Marine

The Department of Agriculture, Food and Marine's statutory role is to support the Minister for Agriculture in the formulation and evaluation of policies for Agriculture, Fisheries, Food, Forestry and the Rural Environment.

The Department of Agriculture, Food and Marine is responsible, inter alia, for the regulation of agriculture, fisheries and food industries through national and EU legislation. It is also responsible for monitoring and controlling animal and plant health and animal welfare. Officials conduct inspections of veterinary practitioners, farmers and keepers of animals, licensed merchants (retailers), pharmacies (engaged in the sale and supply of veterinary medicines), wholesalers of veterinary medicines and compound feed manufacturers of both medicated and non-medicated foodstuffs to assess compliance with legislation[31] and approved standards[32].

The Department conducts a combination of both announced and unannounced inspections.

(a) Announced inspections are carried in circumstances where a facility applies for a wholesale licence, licenced merchant's licence (retail licence for sale and supply of veterinary medicines), internet licence or manufacture of medicated feed licence. Parties are notified in advance to ensure that the relevant personnel are present in order to enable relevant personnel to be present and to enable the officials carrying out the inspection to inform the applicant of relevant conditions which must be satisfied in order to get licence approval.

(b) The Department carries out unannounced inspections to detect any non-compliance with licence conditions of breaches of legislation. Parties do not receive advance notice of these inspections so that operating practices cannot be visibly altered and non-compliances or breaches covered up such that they are not readily obvious at the point of the inspection.

[31] European Communities (Animal Remedies)(No.2) Regulations 2007 as amended, transposed from Directive 2001/82 and Medicated Feed Directive 90/167EEC-SI 176 of 1994.

[32] http://www.agriculture.gov.ie/aboutus/aboutthedepartment/

2.10 Analysis

In order to gain an insight into national and international inspection policies, a questionnaire was circulated to approximately thirty two national and international regulators. The purpose of the questionnaire was to gain an understanding of the inspection approaches (i.e. announced or unannounced) adopted by various Regulators.

The questionnaire was circulated to the following Irish Regulators who have inspection functions in the State:

- Health Service Executive (HSE)
- Health and Information Quality Authority (HIQA)
- Irish Medicines Board (IMB)
- Mental Health Commission (MCH)
- Veterinary Council
- Radiological Protection Institute of Ireland (RPII)
- Environmental Health Association of Ireland
- Health and Safety Authority (HSA)
- Environmental Protection Agency (EPA)
- Department of Agriculture Food and the Marine
- Department of Social Protection
- National Employment Rights Agency (NERA)

The questionnaire was also circulated amongst the following international regulators who carry out inspections of pharmacies:

- General Pharmaceutical Council of Great Britain
- Health Care Inspectorate Netherlands
- Italian Medicines Agency
- Australian Pharmacy Council - Pharmacy Regulation Authority SA (PRASA), Pharmacy Regulation Board of Western Australia, Pharmacy Council of New South Wales & Tasmanian Pharmacy Authority
- Alberta College of Pharmacists
- Ontario College of Pharmacists
- Care Quality Commission UK
- Department of Health Social Services & Public Safety Northern Ireland
- DG Inspection/Dispensing Division - Belgium
- Finnish Medicines Agency
- Norwegian Medicines Agency
- National Authority of Medicines and Health Products - Portugal
- Spanish Agency for Medicines and Health Products
- Pharmacy Council of New Zealand
- National Association of Boards of Pharmacy USA
- Department of Health and Human Services, USA

2.11 Methodology

a) The organisations were sent an email inviting them to complete the PSI Inspection Policy Questionnaire[33].

b) 19 Regulators had responded to the questionnaire at the time this report was completed. The responses received are available at Appendix 2.

2.12 Findings

a) A table summarising questionnaire responses is available at Appendix 3.

b) Recurring comments in relation to the **benefits of announced inspections** from respondents include:

- 11 respondents said that inspections were announced to allow important or relevant people to be present for the inspection
- 7 respondents said that announced inspections ensured documentation was readily available for review
- 4 respondents indicated that announced inspections increased efficiency for the inspected party

c) Recurring comments in relations to the **benefits of unannounced inspections** from respondents include:

- 8 respondents confirmed that unannounced inspections provide a realistic picture or an accurate snapshot of daily practices
- 6 said unannounced inspections assist in achieving on-going and continuous compliance
- 6 respondents use unannounced inspections to follow up on the previous inspection's findings
- 3 respondents said that unannounced inspections were a better use of resources and inspectors' time

[33] The questionnaire was hosted by SurveyMonkey: an online survey development company which allows organisations and individuals to develop surveys which can be completed online by respondents.

Section 3: Announced vs Unannounced Pharmacy Inspections: PSI Pilot Study

Part A: A Comparison Of Inspection Outcomes

Part B: A Comparison Of Resources

Part A: A Comparison Of Inspection Outcomes

A pilot study was initiated to investigate whether the provision of 24 hours advance notice of inspections would impact the outcomes observed at inspection and thereby provide an inaccurate reflection of the level of a pharmacy's compliance with pharmacy and medicines legislation.

3.1 Methodology

(a) 40 announced inspections were carried out by authorised officers over the months of December 2013 and January 2014.

(b) Superintendent Pharmacists were provided 24 hours advance notice of the inspection in each case. The opportunity to defer the inspection was not afforded.

(c) Authorised Officers carried out the inspection according to current inspection criteria and entered details of the outcomes of the inspection in the PSIs Case Management System (CMS).

(d) Authorised Officers noted whether changes to staff rotas or additional staff were employed, subsequent to the announcement of the inspection.

(e) The level of non-compliant outcomes from announced inspections conducted in December 2013 and January 2014 were compared with non-compliant outcomes from unannounced inspections conducted in 2013. As the number of announced and unannounced inspections was not equal, the levels of non-compliances were stated as percentages for comparison purposes.

3.2 Comparison

1) Inspection Outcomes

a) When comparing the level of non-compliance between the announced and unannounced inspections, significant improvements were noted in the following areas:

- The display of the Certificate of Registration for the Supervising Pharmacist improved by 13%
- The completion of all entries in the Duty Register for the previous 2 months improved by 17%
- Entries in Duty Register being maintained contemporaneously improved by 9%
- The completion of entries in error/incident logs improved by 15%
- The cleanliness of the dispensary improved by 7%
- The appropriate labelling of medicinal products which had been removed from their original packaging improved by 14%
- The storage of all Schedule 2 & 3 Controlled Drugs in the CD Safe improved by 8%
- The endorsing of prescriptions improved by 9%.

b) In all other areas inspected, there were no significant differences[34] in the levels of non-compliances noted.

[34] Differences less than 6% were deemed not significant

c) It was not possible to complete a comparison of the levels of non-compliances in the areas of nursing home supply or the supply of veterinary medicines as the numbers of pharmacies providing these services on announced inspections was too small to provide a meaningful comparison. [35]

Details of the inspection outcomes comparison are set out in Appendix 4.

2) Inspection Staffing Arrangements

a) 29/40 pharmacies (73%) in which announced inspections were carried out made no changes to staffing arrangements in preparation for the inspection.

b) In the 11 pharmacies where staffing arrangements were changed, the following changes were noted:

Superintendent Pharmacist attended inspection	5
Supervising Pharmacist changed hours to attend inspection	2
Pharmacist started work early	2
Extra Pharmacist scheduled	2

Part B: A Comparison Of Resources

The implementation of announced and unannounced inspection policies differ in their use of resources including staff time and expenses. The PSI carried out an analysis of the resources required to conduct a sample month of unannounced inspections in 2013 and the projected resources which would be required to conduct the same sample month of inspections on an announced basis.

3.3 Background

(a) The average compliance inspection lasts 1.5 – 2 hours. Typically an inspector would carry out three unannounced compliance inspections in the working day. However, in circumstances where compliance inspections may exceed the 2 hour timeframe, an inspector may be unable to complete all three inspections. Therefore in circumstances where inspections are to be announced, a maximum of two compliance inspections can be scheduled per day, in order for the inspector to guarantee attendance at the pharmacy and to allow for any additional time which may be required. This has an impact on scheduling and the resource of inspectors' time.

(b) When carrying out compliance inspections, inspectors claim expenses for subsistence, mileage and overnight accommodation, as applicable. Reimbursement rates are set out at Appendix 5.

(c) The 2014 Service Plan for the PSIs Inspection & Enforcement (I & E) Unit outlines the operational objectives for 2014.The Service Plan forecasts 450 compliance inspections to be carried out in 2014, along with other inspections and additional functions carried out by staff of the I&E Unit as follows:

- 200 follow up inspections
- 75 new opening / new registration inspections
- 35 investigation cases
- Management of 50 concerns referred to I&E from Fitness to Practice and Legal Affairs, and members of the public
- Management of 10 prosecutions files
- Management of 10 complaints files

[35] Only 10 pharmacies inspected in the pilot study engaged in the provision of services to patients in nursing homes. Only 6 pharmacies inspected in the pilot engaged in the sale and supply of animal remedies.

The inspection objectives outlined above are based on the assumption of an unannounced inspection policy, and approximately three systems inspections being carried out per inspector, per day out of the office conducting inspections.

3.4 Methodology

(a) August 2013 was selected as the sample month of inspections for review. 45 unannounced compliance inspections were carried out by five inspectors of the PSI during this month. The inspections were carried out in counties: Meath, Kilkenny, Wicklow, Galway, Leitrim, Kerry and Cork. This was considered representative of an average inspection month in the context of distances travelled.

(b) The inspection resources (mileage, subsistence, inspectors time/scheduling) required for this month were noted.

(c) The inspection resources (mileage, subsistence, inspectors time/scheduling) for the same month, assuming that the same pharmacies were inspected by the same number of inspectors, but that the inspections were carried out on an announced basis (2 inspections per day) were determined.

(d) A comparison of resources was carried out.

3.5 Comparison

A detailed comparison is included in Appendix 6

A summary table of findings is included below:

Compliance Inspections: August 2013			
	Unannounced	**Announced**	**Difference**
Number of Inspections	45	45	n/a
Inspection Days	17	25	+ 8 days
Mileage	2730km	3707km	+977km
Overnights	2	6	+4 nights

3.6 Findings

The comparison indicates the following implications on PSI resources:

a) There would be an increased cost to the PSI for travel and subsistence expenses due to increased mileage and increased overnight stays associated with an announced inspection policy. For August 2013, this increased cost relates to:

- An additional 977km travel expenses (estimated cost of €594.79[36]).
- Four additional overnight accommodation/subsistence expenses (estimated cost of €435.96[37])

b) The impact of increased travel and inspection scheduling requirements results in an estimated additional 8 days per month being required to carry out the same number of inspections using an unannounced inspection policy.

[36] Based on mileage expenses of 60.88 cent per kilometre
[37] Based on overnight detention rate of €108.99

The projected increased demand on inspector's time, resulting from increased travel times may lead to reduced efficiencies and may impact the ability of the Inspection and Enforcement team to meet targets set out in the Service Plan 2014.

2014 Service Plan		
	Announced	**Un-announced**
Pharmacy Systems Inspections	450	450
Systems Inspections per 'Inspection Day'	2	3
Pharmacy Systems 'Inspection Days'	225 days	150 days

c) Increased administrative costs were associated with an announced inspection policy. An estimated period of approximately 3 hours was spent notifying 40 inspected parties of their upcoming announced inspection in January 2014 as part of a pilot operation carried out by the PSI. Each party received an email from the PSI and a telephone call as part of this notification process.

Section 4: Stakeholder Comments

The PSI consulted with a number of key stakeholders in relation to the proposed change in PSI inspection policy. The consultation was targeted and the following stakeholders were contacted for submissions on the matter by way of letter dated 23rd December 2013[38] :

1. Department of Health
2. Irish Pharmacy Union
3. Irish Patients Association
4. Patient Focus
5. Health Information Quality Authority
6. Mental Health Commission
7. Health Services Executive
8. Irish Medicines Board
9. Hospital Patient's Association of Ireland

The PSI received a submission from 6 of the 9 of the stakeholders contacted.[39]

The main themes identified in the submissions are presented below.

4.1 Department of Health

The Department of Health's statutory role is to support the Minister for Health in the formulation and evaluation of policies for the health services. The PSI has a reporting relationship to the Department of Health.

The Department of Health does not support the conduct of unannounced inspections.
The Department maintains that patient safety and public protection demand that a high level of standard is maintained at all times in pharmacies, as in other services, and that this is best regulated within the confines of unannounced inspections. They note that unannounced inspections are standard practice in other standard service areas and this should be replicated in the pharmacy sector.

4.2 Irish Pharmacy Union (IPU)

The IPU is the representative and professional body for community pharmacists.

The IPU welcomes and strongly supports the proposal that pharmacy owners would receive advance notice of these inspections. It states that the current system of unannounced inspections means that, in many cases, there is a risk to patient safety associated with a busy pharmacist's attention being taken away from their professional duties as they attempt to produce various documents and policies following the unexpected appearance of the inspector. The IPU submits that a single day's notice falls short of what would be reasonably required to change staff rosters and other arrangements. It is suggested that one week's notice might be more appropriate.

4.3 Irish Patients Association (IPA)

The IPA is an independent, voluntary patient advocate organisation.

The IPA is not in favour of having unannounced visits for routine inspections as there is a perception that announced inspections weakens the regulatory process insofar as an opportunity can be created or perceived

[38] A copy of the letter is included in Appendix 7
[39] A copy of the responses is included in Appendix 8

to be created whereby a facility gets valuable time to better present their position. Notwithstanding this the IPA suggests that there might be a case for announced inspection visits with supporting criteria (e.g. clear previous audit etc.) However, they caution that where it might be an option to carry out inspections on this basis, it would be necessary to have governance safeguards in place to ensure that it does not become the norm to suit business needs and not regulator governance.

4.4 Patient Focus

Patient Focus is a national patient advocacy organisation.

It is Patient Focus' strong view that unannounced inspections provide safeguards for patients and the general public in a way that announced inspections cannot. The response cautions that the change in practice envisaged by the PSIs proposal would weaken the ability of the PSI to provide the necessary safeguards required to protect patients and indeed the general public. It suggests that the proposed change in policy could also lead to a lessening of the trust now enjoyed by the PSI in the performance of their compliance functions and indeed in the perception of the accountability of pharmacists. Notwithstanding this, the letter also states that perhaps an appropriate solution may be the use of both announced and unannounced inspections.

4.5 Health Information and Quality Authority (HIQA)

HIQA are an independent authority responsible for driving quality, safety and accountability, inter alia, in residential services for children, older people and people with disabilities in Ireland.

HIQA have started to conduct announced inspections in their ongoing post registration work. They state that that they are placing increased emphasis on the objective of driving improvement within health and social care services as well as monitoring compliance with standards and regulations. They note that announced inspections of some services enables greater access to information in terms of governance and safety systems that may not be available through an unannounced inspection. However, they recognise that a universal application of announced inspections in what is a key service user/patient safety issue, might damage public confidence in the existing system. HIQA also notes that moving to a 24 hour notice period for inspections may address issues such as staffing levels/arrangements, but could be viewed as introducing an opportunity to enable the provider to introduce a "temporary fix" to enable an assessment of compliance. They raise concern that such a system would need to be underpinned by a very robust system of ongoing risk assessment, informed by intelligence on how an operator is conducting their business, enabling the use of any such information as evidence in any enforcement or conduct proceedings. In this instance, HIQA suggests that the any change in the PSI's inspection policy should not include universal application of announced inspections.

4.6 Mental Health Commission (MHC)

The Mental Health Commission is an independent statutory body responsible for regulating and monitoring mental health services.

The Mental Health Commission note that unannounced inspections are perceived as best practice and generally provide a better insight than announced inspections (from a societal and political perspective). The Commission notes that from a practical perspective, the announcement of an inspection can be useful, in that files, other documents and relevant personnel are readily available. The Commission also note that a combination of announced and unannounced inspections may provide a good overall view. It is suggested that an announced inspection followed by an unannounced inspection, if deemed appropriate may also be worthy of consideration.

Section 5: Conclusion & Recommendations

5.1 Conclusion

The PSI is responsible under the Pharmacy Act for the regulation of pharmacists and pharmacies and the supervision of compliance with the Pharmacy Act 2007 and instruments made thereunder. It carries out these functions "having regard to the need to protect, maintain and promote the health and safety of the public". One of the principal mechanisms the PSI has to achieve this function is through the inspection retail pharmacy businesses. Since the commencement of Part 7 of the Act, which sets out the inspection and investigation powers of the PSI, pharmacy compliance inspections have generally been conducted on an unannounced basis.

The principal reasons for unannounced inspections are:

- To provide assurance to the public that the regulatory system for pharmacists and pharmacies is robust and acts in the best interests of patients and the public.
- To obtain an accurate assessment of the management of the pharmacy and its compliance with pharmacy and medicines legislation, on a day to day basis, as experienced by patients.

The PSI reviewed international best practice in regard to the conduct of announced and unannounced pharmacy inspections. The findings of this review shows that the majority of international pharmacy regulators favour an unannounced inspection model, insofar as compliance inspections are concerned, because they are perceived to provide a true and accurate representation of the manner in which the pharmacy is operated on a day to day basis. While certain regulators provide advance notice of compliance inspections to pharmacies, it is noteworthy that in the majority of these cases (2/3) the exact date of the inspection is not notified to the inspected party. The review of international pharmacy regulators in this report indicates that the PSIs current unannounced inspection model is in keeping with the majority of international regulatory pharmacy practices reviewed.

The PSI reviewed national practice in regard to the conduct of announced and unannounced inspections. The findings of this review show that other national healthcare regulators/agencies generally support the use of unannounced compliance inspections because they represent a clearer insight into the reality of the service as experienced by residents/patients. One healthcare regulator noted that they have started to use a combination of announced and unannounced inspections to achieve their objective of driving improvement within health and social care services as well as monitoring compliance with standards and regulations. Announced inspections tend to be favoured in pharmaceutical industry to ensure that relevant personnel are present and that certain documentation and facilities are available/accessible for review. The review of national inspection policy regulators in this report indicates that the PSIs current unannounced inspection model is generally consistent with national inspection policy.

The pilot study conducted by the Inspection and Enforcement Unit of the PSI, comprising 40 announced inspections, provided data which showed marginal change in the compliance results between announced and unannounced inspection types. This suggests that pharmacy practices were generally consistent irrespective of whether the inspection was announced or unannounced. Significant improvements in compliance outcomes in the completion of the duty register, error records and labelling of medicines which had been removed from their primary packaging. Few pharmacies availed of the 24 hour notice period to change staffing arrangements at the pharmacy for the purposes of the inspection.

The PSI carried out an analysis of the resources required to conduct a sample month of unannounced inspections in 2013 and the projected resources which would be required to conduct the same sample month of inspections on an announced basis. The findings indicate that the adoption of an announced inspection policy is expected to result in an increase in costs to the organisation due to increased administration, travel and subsistence expenditure and travel time. This may impact on the ability of the PSI to reach the Service

Plan 2014 targets of 450 compliance inspections by year end. The increased costs and increased demand on inspectors' time must be weighed against the objectives sought from an announced inspection policy.

The PSI consulted with a number of key stakeholders in relation to the proposed change in PSI inspection policy to seek their considered views on the proposal. The responses received strongly support the conduct of unannounced compliance inspections. A number of respondents indicated that a combination of announced and unannounced inspections may also be appropriate. Some respondents considerannounced inspections may only be appropriate in certain limited circumstances e.g. following the successful completion of unannounced inspections and/or in cases where a clear previous audit has taken place, however, they cautioned against the use of announced inspections in circumstances where patient safety issues have been identified. One stakeholder welcomed the proposal of announced inspections stating that the current unannounced inspection model poses a risk to patient safety as a pharmacist's attention is drawn away from professional duties in order to procure documents for the inspector. It is noteworthy that the strong view and policy of the Department of Health favours unannounced inspections in the pharmacy sector and other areas of health.

5.2 Recommendations

The PSI believes that the current inspection policy, whereby compliance inspections are not announced to inspected parties in advance, is generally consistent with national inspection practices, international pharmacy inspection practices and stakeholder opinion. The PSIs unannounced inspection policy is also consistent with the policy of the Department of Health, with whom the PSI have a direct reporting relationship.

The first inspection cycle of all pharmacy inspections in the State is due for completion by mid-2015 at which point the PSI will have, for the first time under the Pharmacy Act 2007, established a compliance baseline. Having established that baseline, the PSI is committed to using that information to refine and develop the inspection and enforcement policy for the period 2015-17. In the context of future strategy, the PSI is committed to considering the feasibility of all compliance tools and potential approaches which may be appropriate to assure patient safety and which can efficiently achieve the best compliance standards in the pharmacy sector. This may include the potential use of self-assessment, risk based approaches to inspection, a change to practice focused inspections, and/or Superintendent Pharmacist led self-audit. There may also be circumstances where the utilisation of announced compliance inspections may be appropriate e.g. in cases of good and consistent audit history etc.

However, until such time as the inspection strategy is further informed or defined, and/or greater information from tools such as self-assessment or future inspection cycles has been gathered, the Executive would caution against any commitment to an announced inspection policy for compliance inspections.

The Executive of the PSI recommends the following:

1. To continue to develop a quality and risk system for inspecting pharmacies in collaboration with stakeholders:
   - in line with evolving good regulatory practices and the needs of patients and the pharmacy sector
   - having regard to the various inspection tools/and baseline information available.

2. To re-visit the potential for the use of announced compliance inspections in future strategy developments and in response to improving compliance standards and audit practices within the pharmacy sector.

3. To maintain the current unannounced inspection policy, in keeping with the existing PSI Corporate Strategy and international and national practices.

Signed

Marita Kinsella

22 Jan 14

Ms Marita Kinsella B.Sc. (Pharm), B.L., M.P.S.I
Registrar of The Pharmaceutical Society of Ireland

Date

Appendix 1

International Pharmacy Regulators: Use of Announced and Unannounced Inspections

International Regulator	Announced Inspections	Unannounced Inspections	Comments
The Department of Health, Social Services and Public Safety Northern Ireland	✓ Registration inspections	✓ Compliance inspections Follow-up inspections	
The General Pharmaceutical Council (GPhC) UK	✓ Most routine compliance inspections 4-6 weeks notice period provided (specific date not disclosed)	✓ Testing unannounced routine compliance inspections Inspections/investigations where there is information to suggest there may be a risk to patient safety.	The GPhC indicate that they intend to move to unannounced compliance inspections ultimately
The Pharmacy Registration Board of Western Australia	✗	✓ Compliance inspections	All inspections are conducted on an unannounced basis
The Pharmacy Council of New South Wales	✓ new pharmacy openings relocations or where there had been a substantial change to the premises	✓ Compliance inspections, follow-up inspections, or inspections in relation to complaints	
The Pharmacy Regulation Authority South Australia	✓ compliance inspections 6 months notice period provided (specific date not disclosed)	✓ Follow up inspections or where there is information to suggest there may be a risk to patient safety	

The Tasmanian Pharmacy Authority	✓ new pharmacy openings, or where there have been alterations to the pharmacy premises	✓ Compliance inspections, follow up inspections	
Health Care Inspectorate The Netherlands	✓ Routine compliance inspections or inspections where there may be risk to patient safety but where there is no previous evidence of malpractice 2-6 weeks notice period of inspection Or occasionally 24 hours notice	✓ Inspections where there is information of concern from two or more sources, where previous non-compliance has been identified or criminal offences suspected.	
Ontario College of Pharmacists Canada	✓ New pharmacy openings Compliance inspections 6 month notice period provided (specific date not disclosed)	✓ Follow up inspections	
Alberta College of Pharmacists Canada	✗	✓ Compliance inspections	All inspections are conducted on an unannounced basis

The Pharmaceutical Society of Ireland	✓ new pharmacy openings or relocations	✓ Compliance inspections Investigations	

Appendix 2

PSI Questionnaire on Inspection Policy

Section A: About your Organisation

**Please note, you cannot press 'the back arrow' on your browser at any time during the survey. If you wish to go back to make any changes to your responses, use the 'previous' button at the bottom of the page.*

1. Name of Organisation

2. Who do you inspect?

3. What is the legislative authority which permits the organisation to conduct inspections?

4. Do you publish inspection reports?

PSI Questionnaire on Inspection Policy

Section B: Inspection Types

1. What types of inspections do you carry out?

- ◯ Mixture of announced and unannounced inspections
- ◯ Announced inspections only
- ◯ Unannounced inspections only

Section C: Mix of Announced Inspections & Unannounced Inspections

Please complete this section if you carry out **BOTH** announced and unannounced inspections.

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

2. What notification period is provided to the inspected parties?

3. How long does a typical inspection last?

4. Why are parties notified of the inspection? ***(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)***

5. What are the perceived benefits of notifying parties in advance of these inspections?

6. <u>Unannounced Inspections</u>

Please provide a brief description of the purpose of the unannounced inspections.

7. How long does a typical inspection last?

8. Why are parties not notified of the inspection? ***(Please list reasons)***

Section D: Announced Inspections Only

Please complete this section if you carry out announced inspections only.

1. Please provide a brief description of the purpose of the annouced inspections

2. How long does a typical inspection last?

3. Why are parties notified of the inspection? ***(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)***

4. What are the perceived benefits of notifying parties in advance of these inspections?

Section E: Unannounced Inspections Only

Please complete this section if you carry out unannounced inspections only.

1. Please provide a brief description of the purpose of the inspection

2. How long does a typical inspection last?

3. Why are parties not notified of the inspection? ***(Please list reasons)***

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

PSI Questionnaire on Inspection Policy

Section F: Other Comments

1. Please enter any additional comments below.

Section G: Contact Information

1. Questionnaire completed by:

2. Position:

3. Contact Details (phone and email):

Healthcare

Design Survey | Collect Responses | Analyze Results

View Summary
Browse Responses
Filter Responses
Crosstab Responses
Download Responses
Share Responses

Default Report

Displaying 1 of 24 respondents

Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
193.176.225.14

Response Started:
Tuesday, January 7, 2014 4:45:08 AM

Response Modified:
Tuesday, January 7, 2014 5:46:12 AM

1. Name of Organisation

Health Care Inspectorate (of the Netherlands), a separate administrative unit of the Ministry of Health.

2. Who do you inspect?

Pharmacists, dispensing GP's in rural area's, hospital pharmacists, other healthcare professionals acting in medication prescribing, dispensing and administration.

3. What is the legislative authority which permits the organisation to conduct inspections?

In descending order the main element of the legislative structure: the Health law, the General Administrative Law act, the Quality law for healthcare establishments, the law for individual Healthcare Practitioners, the Medicines' law.

4. Do you publish inspection reports?

Yes, but there are exceptions. Investigations concerning sexual harassment are usually not published. Reports of individual healthcare practioners are published only if repeated inspection results are sub standard. The publication process is ruled by a law on free acces to governmental/administrative information, the Wet Openbaarheid Bestuur. An internal section is dedicated to manage the publication proces, i.a. to prevent unneccessary disclosure of personal data and certain sensitive company info. Stakeholders are informed before publication and allowed to file a formal objection at the level of the Ministry and subsequently to issue a court cmplaint, if wanted.

1. What types of inspections do you carry out?

Mixture of announced and unannounced inspections

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

To determine if there is compliance to law and other relevant regulations, to detect potential risk to citizens/patients.

2. What notification period is provided to the inspected parties?

There is no fixed period. It is ususlly between one and six weeks.

3. How long does a typical inspection last?

Half a working day (4 hours).

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

Presence/availability of the legally responsible pharmacist, physician, nurse, quality official. Efficiency of the visit, e.g. documentation at hand, scheduled round etc. Possibility to speak the board of directors/commissioners. No previous signals of avoidance/malpractice. In most cases preparation/cover-up before inspection is not very effective. This form of inspection-bias is ususally recognisable and of little effect to the visit outcomes, but only if well trained and professionally educated inspectors are available.

5. What are the perceived benefits of notifying parties in advance of these inspections?

Especially physicians and nurses have difficulties in freeing time in daily patient care schedules during unannounced visits. Other key professionals are regularly not available (parttime work, holidays, external meetings, continuing education, parental leave etc.). Announcing the visit avoids this kind of inefficiencies.

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

In general not very different. Signals from >2 different sources and/or of repated non-compliance or substandard performance may be an important reason. Supposed criminal offences: instead of the inspection team an intervention team is led by the public prosecutioner, inspectors assist.

7. How long does a typical inspection last?

Same as 3. unless problems are encountered, which is not regular but more frequent in these cases. There is also a tendency to have less qualified inspectors carry out several very short (1 hour max) monitoring visits a day, filling in electronic forms on a tablet. This approach seems to work in assessing compliance to e.g. general hygiene.

8. Why are parties not notified of the inspection? *(Please list reasons)*

Sometimes there is a known history of problems and non-compliance which motivates the inspector/inspection team to make a visit unannounced. Important also is the political commitment of the Minister to the wish of Parliament to carry out if not all, most inspection visists unannounced. In practice this can be realised with larger organisations (with large staff and sometimes separate quality departments) such as hospitals but is not practical for an individual GP.

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

We currently work many times with semi-unannounced visits: pharmacies are informed max. 24 hrs. before, which enables them to have the important people available during the visit. This compromise was made to increase the level of trust of the general public in objective results of our inspection visits, while maintaining a workable planning and travel in practice.

Displaying 2 of 24 respondents

Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
89.101.136.129

Response Started:
Tuesday, January 7, 2014 6:04:10 AM

Response Modified:
Tuesday, January 7, 2014 6:24:38 AM

1. Name of Organisation

Irish Medicines Board

2. Who do you inspect?

Manufacturers and wholesalers of medicinal products (human & veterinary) Medical device manufacturers and authorised representatives Tissue & Cells establishments Blood establishments Organ establishments Marketing Authorisation holders offices Offices where pharmacovigilance activities are undertaken Sites where clinical trials are undertaken

3. What is the legislative authority which permits the organisation to conduct inspections?

IMB Act and Bill National legislation that transposed Directive 2001/82 and 2001/83, as amended relating to medicines National legislation that transposed EU Directives relating to quality and safety of Blood, Tissues & Cells and Organs

4. Do you publish inspection reports?

No

1. What types of inspections do you carry out?

Mixture of announced and unannounced inspections

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

The vast majority of IMB inspections are announced. The purpose of the inspections would be to check compliance with licensing conditions and/or approvals granted against the applicable standards Inspections are consider as either routine or non-routine

2. What notification period is provided to the inspected parties?

Generally six weeks notice is given

3. How long does a typical inspection last?

This varies from 2 hours for a small wholesaler who supplies the grocery trade to 5 days with a team of inspectors for a large manufacturer

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

So that specific persons are present for the course fo the inspection e.g. QP To ensure that there is no clash between inspections being performed by other agencies In the case of foreign inspections a letter of invitation from the company is often required to process visa applications In the case of foreign inspections up front payment of flights is required

5. What are the perceived benefits of notifying parties in advance of these inspections?

Best use of time on site Site can prepare for the inspection and have documents ready for review on the first day For non-routine inspection the correct timing is in some cases critical in order to see a qualified process / equipment so inspection is aligned to site validation schedule

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

Unannounced Inspections may be conducted to check the compliance status of a site or company

7. How long does a typical inspection last?

An unannounced inspection would be quite focussed and would generally be of short duration - 1 day

8. Why are parties not notified of the inspection? *(Please list reasons)*

Unannounced inspections may be conducted where there is a suspected breach of good practice and there is a likelihood that the evidence would be removed if it was known that an inspection was to take place.

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

'Unannounced' may also be used to describe short announced inspection where one days notice or less is given

Displaying 4 of 24 respondents

Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
67.211.118.137

Response Started:
Tuesday, January 7, 2014 6:30:34 AM

Response Modified:
Tuesday, January 7, 2014 6:48:43 AM

1. Name of Organisation

Ontario College of Pharmacists

2. Who do you inspect?

Community Pharmacies

3. What is the legislative authority which permits the organisation to conduct inspections?

Drug and Pharmacies Regulation Act

4. Do you publish inspection reports?

Just results; Pass Pass with Conditions Fail Please see:
http://www.ocpinfo.com/client/ocp/OCPHome.nsf/web/About+Public+Register#Posting

1. What types of inspections do you carry out?

Mixture of announced and unannounced inspections

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

Announced currently are only for new store openings.

2. What notification period is provided to the inspected parties?

For new openings, the time of inspection is determined based on opening date requested. The inspector arranges a mutually convenient time with the pharmacy. For all other inspections, a Prior Notice Letter is sent to the pharmacy notifying them that an inspector will be visiting within the next 6 months. They are invited to contact the inspector if there are specific days of the week that would work better or if they plan on being on vacation but no specific time is arranged.

3. How long does a typical inspection last?

3-6 hours

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

Only for new openings since pharmacy is not yet in operation. However we are changing our inspections to be more practice based and will be assessing the need to make appointments.

5. What are the perceived benefits of notifying parties in advance of these inspections?

In our current notifications, we inform them that we will be inspecting within the next 6 months and give them an opportunity to review any policies, guidelines, legislation or current issues that they wish to discuss with the inspector during the visit. They are encouraged to engage their staff as our goal is to provide guidance and education to improve pharmacy practice. If we move to a more practice based assessment where we plan to conduct chart reviews, it may be necessary to notify parties to that adequate staff are present during the visit. In very busy pharmacies, it may not be possible to have meaningful, uninterrupted dialogue with pharmacists.

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

as above

7. How long does a typical inspection last?

as #3

8. Why are parties not notified of the inspection? *(Please list reasons)*

Currently specific appointments are not made with pharmacies mainly for logistic reasons.

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

Please feel free to contact me if you wish to discuss further. I am also hearing your findings as we too will be embarking on new processes.

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Response Type:
Normal Response

Collector:
Web Link
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Custom Value:
empty

IP Address:
96.53.106.181

Response Started:
Tuesday, January 7, 2014 9:21:27 AM

Response Modified:
Tuesday, January 7, 2014 9:32:51 AM

1. Name of Organisation

Alberta College of Pharmacists, Edmonton, Alberta, Canada

2. Who do you inspect?

Pharmacy teams (pharmacies, pharmacists, pharmacy technicians) in community practice settings. We are expanding to include satellite pharmacies, primary care networks, consultant pharmacist practice settings, long term care practice settings.

3. What is the legislative authority which permits the organisation to conduct inspections?

Pharmacy and Drug Act under the provincial (Alberta) government which focuses on the operation of licensed pharmacies. We are seeking amendments to the Health Professions Act as well to allow our inspectors to be appointed under this act which focuses on practice, although our inspectors, known as pharmacy practice consultants, already complete assessments that are 90% practice based.

4. Do you publish inspection reports?

No but each pharmacy licensee receives an action report listing the deficiencies. They must identify who is responsible within their team to correct them and do so within 30 days.

1. What types of inspections do you carry out?

Unannounced inspections only

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

No Response

2. What notification period is provided to the inspected parties?

No Response

3. How long does a typical inspection last?

No Response

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

5. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

No Response

7. How long does a typical inspection last?

No Response

8. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

The purpose of the inspection or what we call an assessment is to provide monitoring and support to enhance pharmacy practice in the areas of quality care and safety. We focus on 90% practice and 10% operations. We believe that good operations support good practice. We address lean work flow management for operations and use chart stimulated recall to assess practice.

2. How long does a typical inspection last?

3.5 to 4 hours depending on the performance segmentation of the pharmacy. Pharmacies are rated as low, medium or high performing.

3. Why are parties not notified of the inspection? *(Please list reasons)*

Easier for our consultants to manage their schedules and work flow

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

More efficient territory management for our consultants We see the pharmacies in their natural state, not artificial as the pharmacies try to "clean up" before we come. Allows us to set realistic expectations for the pharmacy when we write up their deficiencies as SMART goals (specific, measurable, achievable, realistic, timely)

1. Please enter any additional comments below.

No Response

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Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
86.42.95.67

Response Started:
Tuesday, January 7, 2014 9:24:21 AM

Response Modified:
Tuesday, January 7, 2014 9:30:39 AM

1. Name of Organisation

Mental Health Commission - Inspectorate of Mental Health Services

2. Who do you inspect?

Approved Centres (inpatient psychiatric units) and other mental health services

3. What is the legislative authority which permits the organisation to conduct inspections?

Mental Health Act 2001

4. Do you publish inspection reports?

Yes - see website

1. What types of inspections do you carry out?

Mixture of announced and unannounced inspections

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

For non-statutory inspections to meet with staff

2. What notification period is provided to the inspected parties?

2 to 3 weeks

3. How long does a typical inspection last?

1 day

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

To sdiscuss aspects of the service

5. What are the perceived benefits of notifying parties in advance of these inspections?

Their presence.

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

For all Approved Centres

7. How long does a typical inspection last?

1 to 2 days

8. Why are parties not notified of the inspection? *(Please list reasons)*

We wish to report on services as they exist and not presented as a showpiece.

1. Please provide a brief description of the purpose of the annouced inspections

Nc Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

No Response

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Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
193.1.210.18

Response Started:
Wednesday, January 8, 2014 1:15:26 AM

Response Modified:
Wednesday, January 8, 2014 1:33:41 AM

1. Name of Organisation

Environmental Protection Agency

2. Who do you inspect?

Licensed facilities under the EPA Acts 1992 as amended and Waste Management Acts 1996 as amended. (Other areas of the Agency conduct other inspections under different legislation; I will complete the form from an EPA licence enforcement aspect only).

3. What is the legislative authority which permits the organisation to conduct inspections?

EPA Acts 1992 as amended; Waste Management Acts 1996 as amended (Other areas of the Agency conduct other inspections under different legislation; I will complete the form from an EPA licence enforcement aspect only).

4. Do you publish inspection reports?

Yes

1. What types of inspections do you carry out?

Mixture of announced and unannounced inspections

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

To ensure: 1. Compliance with licence conditions 2. Check against Agency priority sectoral environmental issues/risks for that year/period 3. Check overall environmental quality of the facility. 4. Meet legislative requirements to conduct visits. 5. Provide public reassurance.

2. What notification period is provided to the inspected parties?

Varies; typically 1-2 days

3. How long does a typical inspection last?

Varies between sectors can be half to full day

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

To ensure contact people are onsite when inspectors arrive.

5. What are the perceived benefits of notifying parties in advance of these inspections?

When contcat person is onsite during the inspection it results in it running more smoothly as they are the most familiar with the licence, its conditions nad requirements. Documents are generally found more quickly and all questions answered on the day of the visit.

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

To ensure: 1. Compliance with licence conditions 2. Check against Agency priority sectoral environmental issues/risks for that year/period 3. Check overall environmental quality of the facility. 4. Meet legislative requirements to conduct visits. 5. Provide public reassurance.

7. How long does a typical inspection last?

Varies between sectors can be half to full day

8. Why are parties not notified of the inspection? *(Please list reasons)*

1. Allows the inspector to get an accurate picture of typical licence compliance on any one day. 2. Public reassurance.

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

No Response

Healthcare

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Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
137.191.224.104

Response Started:
Wednesday, January 8, 2014 1:54:47 AM

Response Modified:
Wednesday, January 8, 2014 2:13:07 AM

1. Name of Organisation

NERA

2. Who do you inspect?

Employers

3. What is the legislative authority which permits the organisation to conduct inspections?

Several pieces of legislation dealing with employment rights including National Minimum Wages Act, Organisation of Working Time Act 1997,Payment of Wages Act 1991, Employment Permits Acts, etc

4. Do you publish inspection reports?

No

1. What types of inspections do you carry out?

Mixture of announced and unannounced inspections

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

to ensure compliance

2. What notification period is provided to the inspected parties?

normally a minimum of 2 weeks

3. How long does a typical inspection last?

Varies depending on co-operation and compliance level

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

to enable employers to have records for inspection and key people available for interview

5. What are the perceived benefits of notifying parties in advance of these inspections?

Records are on the premises when we arrive

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

to check who is in fact working e.g. children or young persons under the Protection of young Persons(Employment) Act 1996 or third country nationals under the Employment Permits Acts. Many of the unannounced visits take place at night and often are undertaked along with other bodies such as Revenue, Social Protection and/or Gardaí

7. How long does a typical inspection last?

Several would take place on any night - say 30 mins

8. Why are parties not notified of the inspection? *(Please list reasons)*

If they are breaching certain legislation, it will not be found only through a records inspection

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

No Response

Displaying 9 of 24 respondents

Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
87.198.189.58

Response Started:
Wednesday, January 8, 2014 2:43:09 AM

Response Modified:
Wednesday, January 8, 2014 2:47:46 AM

1. Name of Organisation

Veterinary Council of Ireland

2. Who do you inspect?

Private Veterinary Practices

3. What is the legislative authority which permits the organisation to conduct inspections?

Veterinary Practice Act 2005 and Amendment Act 2012

4. Do you publish inspection reports?

No

1. What types of inspections do you carry out?

Announced inspections only

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

No Response

2. What notification period is provided to the inspected parties?

No Response

3. How long does a typical inspection last?

No Response

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

5. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

No Response

7. How long does a typical inspection last?

No Response

8. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

1. Please provide a brief description of the purpose of the annouced inspections

To confirm compliance with the standards which apply to the type of practice offered at the veterinary premises

2. How long does a typical inspection last?

2 - 3 hours

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

Certificate Holder needs to be present to sign off on end of inspection report. Certificate Holder is the person legally responsible for the premises and compliance to standards set.

4. What are the perceived benefits of notifying parties in advance of these inspections?

The person will be present and all records which need to be inspected are available. Any issues of concern are discussed with the responsible person.

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

No Response

Displaying 10 of 24 respondents

Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
137.191.231.74

Response Started:
Wednesday, January 8, 2014 4:43:54 AM

Response Modified:
Wednesday, January 8, 2014 5:31:23 AM

1. Name of Organisation

HIQA - Adult Social Care

2. Who do you inspect?

1. "Designated centres" (i.e., residential services for older & dependent people and for people with disabilities)

3. What is the legislative authority which permits the organisation to conduct inspections?

1. Health Act 2007, as amended.

4. Do you publish inspection reports?

Yes

1. What types of inspections do you carry out?

Mixture of announced and unannounced inspections

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

To inform an initial registration decision or to inform a 3-yearly renewal decision

2. What notification period is provided to the inspected parties?

Generally 2 weeks

3. How long does a typical inspection last?

1 day but can be 2 or maore days if a service is large or geographically dispersed

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

To ensure relevant management etc staff are present, that relevant records are available and so that residents and relatives can interact with inspection staff if they wish

5. What are the perceived benefits of notifying parties in advance of these inspections?

It makes the process more efficient, reduces the need for return visits and facilitates resident/relative involvement

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

To ensure critical elements of care and support are in place in regulated services including appropriate staffing etc and that such is the case across the 24/7 week. Also to follow-up previous inspection findings/commitments by providers and ensure actions have been taken as promised.

7. How long does a typical inspection last?

1 day - some may be 2 days is services are large or geographically dispersed

8. Why are parties not notified of the inspection? *(Please list reasons)*

To ensure that the inspection findings are based on the reality of the service as experienced by residents with no scope for manipulation of that reality by other parties

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

No Response

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Response Type:
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Collector:
Web Link
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Custom Value:
empty

IP Address:
137.191.231.74

Response Started:
Wednesday, January 8, 2014 5:48:29 AM

Response Modified:
Wednesday, January 8, 2014 6:25:54 AM

1. Name of Organisation

Health Information and Quality Authority

2. Who do you inspect?

Acute hospitals in Ireland

3. What is the legislative authority which permits the organisation to conduct inspections?

The Health Act 2007 (as amended) established the Helath Information and Quality Authority. Part 9 of Health Act 2007 (as amended) refers to the appointment by the Authority of authorised persons to undertake inspections and investigations.

4. Do you publish inspection reports?

Yes

1. What types of inspections do you carry out?

Mixture of announced and unannounced inspections

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

To assess organisations for their compliance with national standards.

2. What notification period is provided to the inspected parties?

6 weeks

3. How long does a typical inspection last?

4-6 hours

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

Data and documentation are requested in advance for review purposes. Specific responsible individuals need to be present for interviews in order to clarify information submitted prior to the inspection.

5. What are the perceived benefits of notifying parties in advance of these inspections?

Availabilty of key senior members of the organisation for discussion.

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

To assess organisations for their compliance with national standards.

7. How long does a typical inspection last?

3 hours

8. Why are parties not notified of the inspection? *(Please list reasons)*

In order to provide reassurance that standards are complied with as the norm.

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

Unannounced inspections provide a snapshot of compliance with standards. They are limited in their scope but prevent undue preparation by the hospitals in advance of the inspectors' arrival thus perhaps providing a more realistic assessment of compliance of standards as experienced by patients at a given time. Announced inspections allow for observation, review of documentation, discussions with senior staff and an opportunity to gather evidence of compliance with national standards in a more in-depth fashion.

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Displaying 12 of 24 respondents

Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
217.68.69.112

Response Started:
Thursday, January 9, 2014 2:14:11 AM

Response Modified:
Thursday, January 9, 2014 6:06:58 AM

1. Name of Organisation

General Pharmaceutical Council

2. Who do you inspect?

Our role is to inspect registerd pharmacies, ensuring they meet standards for the safe and effective practice of pharmacy.

3. What is the legislative authority which permits the organisation to conduct inspections?

The Pharmacy Order 2010

4. Do you publish inspection reports?

Not at present. But our aim is to do so in future. We launched a new inspection model in a prototype phase on 4 November. This includes the production of a written report detailing the evidence found on inspection and our judgement as to whether the pharmacy meets our standards. In future, this report and a public-facing summary, will be published.

1. What types of inspections do you carry out?

Mixture of announced and unannounced inspections

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

We do not notify a pharmacy of the exact date or time of an inspection. However, we do send a letter which informs a pharmacy that they are due an inspection and that one will be carried out 4-6 weeks folloing receipt of the letter. The purpose at this stage is primarily to raise awareness of our new inspection model and of the standards we expect pharmacies to meet. Ultimately we expect to move to a position of entirrely unannounced inspections.

2. What notification period is provided to the inspected parties?

4-6 weeks.

3. How long does a typical inspection last?

Between 2-3 hours in an individual pharmacy.

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

See answor to Q1. It is primarily to raise awareness of our new inspection model. As we do not notify them of a specific date or time we do not require particular people to be present. Our aim as far as possible is to replicate the experience of a patient who could attend a pharmacy at any point. We expect a pharmacy to meet the standards every day and therefore do not believe we should notify a particular date.

5. What are the perceived benefits of notifying parties in advance of these inspections?

To raise awareness

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

To ensure the standards are being met and to replicate the experience of a member of the public. IN addition we may use unanncounced inspections if we have received particular information about a pharmacy (e.g. from a member of the public or other health body) which indicates there is a risk to patient safety.

7. How long does a typical inspection last?

2-3 hours or possibly less if the purpose is solely to assess one aspect of service delivery.

8. Why are parties not notified of the inspection? *(Please list reasons)*

Because we expect standards to be met every day and not simply when the inspector turns up. And, in the case of following up particular information, we may not want to alert the pharmacy to ensure we obtain an accurate picture of what is happening.

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

No Response

Displaying 13 of 24 respondents

Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
91.216.236.59

Response Started:
Friday, January 10, 2014 2:05:57 AM

Response Modified:
Friday, January 10, 2014 2:22:08 AM

1. Name of Organisation

Radiological Protection Institute of Ireland

2. Who do you inspect?

Those that have custody and use of ionising radiation sources

3. What is the legislative authority which permits the organisation to conduct inspections?

Radiological Protection Act 1991

4. Do you publish inspection reports?

Not currently.

1. What types of inspections do you carry out?

Mixture of announced and unannounced inspections

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

To verify compliance with regulations and licence conditions, to assess safety culture, to observe and where appropriate share good practices in encouraging continual improvement

2. What notification period is provided to the inspected parties?

This varies from a day to a number of weeks depending on the complexity of the facility being inspected and the preparation that may be required

3. How long does a typical inspection last?

This varies depending on the complexity of the facility and the scope of the inspection - from two hours to a full day.

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

In order to have the right people in place which could be the CEO as well as senior technical and possibly clinical people. It is not always appropriate to disrupt on-going clinical practice and sometimes observation of certain procedures have to be planned well in advance in line with clinical schedules.

5. What are the perceived benefits of notifying parties in advance of these inspections?

Having key people available to provide evidence of compliance, maximising opportunities to observe certain procedures

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

Unannounced inspections are most useful when there is a doubt about what has been observed in the planned

inspection; or in following up on intelligence about a facility or practice. It is also useful that the regulated community are aware that this something that the Regulator can and will do from time to time.

7. How long does a typical inspection last?

This varies depending on the complexity of the facility and the scope of the inspection - from two hours to a full day.

8. Why are parties not notified of the inspection? *(Please list reasons)*

As unannounced inspections are most useful when there is a doubt about what has been observed in the planned inspection or in following up on intelligence about a facility or practice then it would be counter productive to announce such an inspection. It is also useful that the regulated community are aware that this something that the Regulator can and will do from time to time.

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

Most of RPII's inspections are announced inspections but is something that we regularly discuss and keep under review with changes in practices and the regulatory environment and would be interested in the results of your analysis.

Displaying 14 of 24 respondents

Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
59.167.91.189

Response Started:
Sunday, January 12, 2014 3:15:38 PM

Response Modified:
Sunday, January 12, 2014 3:43:17 PM

1. Name of Organisation

Pharmacy Regulation Authority SA

2. Who do you inspect?

Registered pharmacy premises (ie pharmacies)

3. What is the legislative authority which permits the organisation to conduct inspections?

The Act - Health Practitioner Regulation National Law (South Australia) Act 2010

4. Do you publish inspection reports?

No

1. What types of inspections do you carry out?

Mixture of announced and unannounced inspections

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

Visits (the term used in this jurisdiction) are conducted on a random basis across a 3 year period of all registered premises. The visits ascertain the level of adherence of the sites to the published standards and guidelines for the operation of registered pharmacy premises. Depending on the level of remedial action required a re-visit may also be required.

2. What notification period is provided to the inspected parties?

Anytime within a six month window.

3. How long does a typical inspection last?

Two hours.

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

The visit program aims to be a co-operative effort between PRASA (the Authority) and the entities operating registered pharmacy premises (pharmacists, registered pharmacy companies and registered pharmacy trusts) to ensure the maintenance of standards of the highest level. Prior notification lends itself to a spirit of co-operation and joint endeavour at least in the initial stages of the process. Provides a potential opportunity for any registered pharmacy premises that may have let slip its agherence to the required standards to review and initiate measures to bring its operations into alignment with the level necessary and expected by the community and consumers.

5. What are the perceived benefits of notifying parties in advance of these inspections?

Taking as much of the adversarial context of the visit program out of the process. Allowing time for reflection at the registered pharmacy premises to be visited. Allowing for appropriate measures to be implemented where necessary in advance of the visit.

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

To confirm on-going adherence to the standards and guidlelnes where either a notification (from a community member) or evidence highlighted during the visit program suggests a lack of commitment at the registered pharmacy premises concerned.

7. How long does a typical inspection last?

Generally less as unannounced visits tend to be targeted to specific issues. One hour.

8. Why are parties not notified of the inspection? *(Please list reasons)*

Ensuring accuracy as to the "actual" situation. Ensuring "actual" commitment as opposed to suggested commitment.

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

No Response

Displaying 15 of 24 respondents

Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
116.212.205.26

Response Started:
Sunday, January 12, 2014 4:26:53 PM

Response Modified:
Sunday, January 12, 2014 4:32:23 PM

1. Name of Organisation

Pharmacy Registration Board of Western Australia

2. Who do you inspect?

Registered pharmacy premises within Western Australia

3. What is the legislative authority which permits the organisation to conduct inspections?

Pharmacy Act 2010

4. Do you publish inspection reports?

No, however a summary of the findings from inspections is included in the Board's Annual report, which can be downloaded from the Board's website at: www.pharmacyboardwa.com.au

1. What types of inspections do you carry out?

Unannounced inspections only

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

No Response

2. What notification period is provided to the inspected parties?

No Response

3. How long does a typical inspection last?

No Response

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

5. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

No Response

7. How long does a typical inspection last?

No Response

8. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

To ensure compliance with the minimum standards as prescribed in the Act

2. How long does a typical inspection last?

1 hour

3. Why are parties not notified of the inspection? *(Please list reasons)*

To ensure that the premises are compliant at all times rather than just compliant when they are made aware of an inspection.

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

Helps develop a culture of ongoing compliance.

1. Please enter any additional comments below.

No Response

Displaying 16 of 24 respondents

Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
210.87.21.10

Response Started:
Sunday, January 12, 2014 4:56:04 PM

Response Modified:
Sunday, January 12, 2014 5:25:56 PM

1. Name of Organisation

Pharmacy Council of New South Wales

2. Who do you inspect?

All pharmacy premises that are subject of a current approval of the Pharmacy Council of NSW (routine inspection at least once every 18 months), pharmacy premises upon receipt of an application for a new pharmacy, application for relocation of exisitng pharamcy premises or following substantial change to the size of the pharmacy premises (reduction or expansion in size; and inspections in relation to complaints matters (ad hoc and at the request of the Pharmacy Council.

3. What is the legislative authority which permits the organisation to conduct inspections?

Section 164A of the Health Practitioner Regulation National Law (NSW)
http://www.legislation.nsw.gov.au/maintop/view/inforce/act+86a+2009+cd+0+N

4. Do you publish inspection reports?

No

1. What types of inspections do you carry out?

Mixture of announced and unannounced inspections

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

Pharmacy premises in relation to applications for a new pharmacy, or relocation of existing premises, or resizing of premises (reduction or expansion);

2. What notification period is provided to the inspected parties?

Date and time of inspection is by agreement between aqpplicant and the inspector

3. How long does a typical inspection last?

approx one hour , excluding travel time which can be considerable

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

Ensure access to the premises, answer questions and sign the inspection form.

5. What are the perceived benefits of notifying parties in advance of these inspections?

Ensure access, ensure the premises are ready to be inspected.

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

Routine inspection of all pharmacy premises in New South Wales at least once every 18 months; inspections in

relation to complaints matters; follow up inspections to check on compliance with legislative requirements (ie have they obtained missing equipment or publications).

7. How long does a typical inspection last?

varies. Routine inspections 30mins - one hour Complaints matters may take longer if this requires discussions with pharmacist and involves an investigation, inspection of documentation/photocopying/photos etc.

8. Why are parties not notified of the inspection? *(Please list reasons)*

Routine inspections - there is no need to give advance notice Complaints matters - may be advance notice if a particular pharmacist is to be interviewed.

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

No Response

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Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
147.69.13.204

Response Started:
Sunday, January 12, 2014 9:30:23 PM

Response Modified:
Sunday, January 12, 2014 9:41:53 PM

1. Name of Organisation

Tasmanian (in Australia)Pharmacy Authority

2. Who do you inspect?

Pharmacy business premises other than those run by the state or federal government

3. What is the legislative authority which permits the organisation to conduct inspections?

(Tasmanian) Pharmacy Control Act 2001

4. Do you publish inspection reports?

No

1. What types of inspections do you carry out?

Mixture of announced and unannounced inspections

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

These are usually by arrangement after alterations to a previously approved premises are completed or when a new pharmacy premises is ready for business

2. What notification period is provided to the inspected parties?

Not formalised in legislation but we generally give about a week's notice.

3. How long does a typical inspection last?

1-2 hours

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

So that the Pharmacist in Charge and/or owner(s) can be present, which makes the inspection more efficient as they can make decisions to immediately rectify any small matters brought to their attention; and discuss/educate re aspects of security, Poisons Act and storage of scheduled medicines, dispensing practices etc. We also encourage them to do a self audit prior to our visit (the Authority provides a form which is also on our website) for this purpose. This should mean everything is more likely to be shipshape.

5. What are the perceived benefits of notifying parties in advance of these inspections?

see Q4 above

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

These are a cyclical process (roughly every 3 years) aimed at ensuring registered pharmacy premises continue to comply with legislation. While they're generally unannounced, we want these inspections to be educative not punitive, and our intention is not to prosecute but to bring them up to scratch. We also inspect without notice if something's

been brought to our attention which might indicate the pharmacy does not comply; or when a previous inspections flagged issues to be addressed.

7. How long does a typical inspection last?

1-2 hours

8. Why are parties not notified of the inspection? *(Please list reasons)*

If we believe their practices might be in breach, possibly intentionally, we don't want to warn them and give them time to hide or destroy evidence; similarly, if issues had been highlighted which required attention and they told us it'd been done, a random (unannounced) inspection would allow us to assess this properly.

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

No Response

Displaying 22 of 24 respondents

Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
137.191.228.131

Response Started:
Thursday, January 16, 2014 6:54:46 AM

Response Modified:
Thursday, January 16, 2014 7:31:35 AM

1. Name of Organisation

Department of Agriculture, food and Marine

2. Who do you inspect?

Veterinary Practitioners, Farmers and keepers of animals, Licensed merchants (retailers), Pharmacists, veterinary wholesalers, compound feed manufacturers of both medicated and non medicated feed, home mixers (farmers that manufacture medicated feed)

3. What is the legislative authority which permits the organisation to conduct inspections?

European Communities (Animal Remedies) (No. 2) Regulations 2007 as ammended, transposed from Directive 2001/82 and Medicated Feed Directive 90/167/EEC- SI 176 of 1994

4. Do you publish inspection reports?

No

1. What types of inspections do you carry out?

Mixture of announced and unannounced inspections

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

The announced inspections are generally when there is an initial application for a wholesale licence, retail licence, internet licence, or manufacture of medicated feed licence

2. What notification period is provided to the inspected parties?

Generally a week

3. How long does a typical inspection last?

Two - three hours

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

Parties are notified so that the relevant personnel are present to enable the inspection to go ahead, also to inform the applicant for a licence of relevant conditions that must be met in order to get licence approval

5. What are the perceived benefits of notifying parties in advance of these inspections?

That information that will be required during inspection will be available at the time of the inspection.

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

To dectect any non compliances with licence conditions or breaches of legislation

7. How long does a typical inspection last?

It depends on what issue is being inspected, it could take anything from an hour to a full day or longer

8. Why are parties not notified of the inspection? *(Please list reasons)*

So that operating practices cannot be visibly altered and non compliances or breaches covered up and not readily obvious at the time of inspection.

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties not notified of the inspection? *(Please list reasons)*

No Response

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

No Response

1. Please enter any additional comments below.

In my experience the unannounced inspections are far more effective in terms of detecting non compliances or breaches of legislation but there can be issues with inexperienced personnel and lack of sufficent information available at the time of inspection.

Healthcare

Design Survey | Collect Responses | Analyze Results

View Summary
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Displaying 23 of 24 respondents

Response Type:
Normal Response

Collector:
Web Link
(Web Link)

Custom Value:
empty

IP Address:
194.32.29.1

Response Started:
Friday, January 17, 2014 1:31:01 AM

Response Modified:
Friday, January 17, 2014 2:11:30 AM

1. Name of Organisation

DHSSPSNI -Medicine Regulatory Group

2. Who do you inspect?

Community pharmacies,other establishments in conjunction with MHRA and VMD . CD Licence holders, management of CDs in hospices, private healthcare providers, Trust hospital pharmacies, ambulance stations. THE FOLLOWING COMMENTS WILL ONLY RELATE TO COMMUNITY PHARMACY INSPECTION.

3. What is the legislative authority which permits the organisation to conduct inspections?

Medicines Act 1968, Human Medicines Regulations 2012, Misuse of Drugs Act 1971 and regulations, Veterinary Medicines Regulations, Pharmacy(NI) Order 1976, Poisons (NI) Order 1976,

4. Do you publish inspection reports?

No

1. What types of inspections do you carry out?

Unannounced inspections only

1. Announced Inspections

Please provide a brief description of the purpose of the annouced inspections

gdsg

2. What notification period is provided to the inspected parties?

gdsg

3. How long does a typical inspection last?

dgsdg

4. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

sdg

5. What are the perceived benefits of notifying parties in advance of these inspections?

dsgfds

6. Unannounced Inspections

Please provide a brief description of the purpose of the unannounced inspections.

sfdgds

7. How long does a typical inspection last?

4 hourss

8. Why are parties not notified of the inspection? *(Please list reasons)*

gsdgffdg

1. Please provide a brief description of the purpose of the annouced inspections

No Response

2. How long does a typical inspection last?

No Response

3. Why are parties notified of the inspection? *(Please list reasons e.g. specific persons need to be present for the inspection, duration etc.)*

No Response

4. What are the perceived benefits of notifying parties in advance of these inspections?

No Response

1. Please provide a brief description of the purpose of the inspection

There are two types of inspection; premises registration inspection and routine inspection of registered pharmacy premises. First type ensures that premises meet the standards for premises as published by the PSNI. Second type monitors and encourages compliance with legislation and professional standards as published by PSNI.

2. How long does a typical inspection last?

2-3 hours

3. Why are parties not notified of the inspection? *(Please list reasons)*

Some soundings several years ago indicated that preference was that inspections were unannounced.

4. What are the perceived benefits of carrying out un-notified inspections for parties involved?

We believe unannounced inspections in some cases may give a more realistic snapshot of how a pharmacy is operating.

1. Please enter any additional comments below.

No Response

Appendix 3

National Regulators that perform a mixture of inspection types

Name of Org	Reasons/Benefits of Announced	Reasons/Benefits of Unannounced	Comments
Irish Medicines Board	• No exact date, most are announced get 6 weeks' notice • 2hours-5days • Ensures important peoples' presence • Ensure no clash with other agencies' inspections • Documentation easily available	• Focussed inspection (1 day) • Suspected breach of best practice • Likelihood inspection would reveal evidence of breach	• 'Unannounced' could also refer to short 24 hours' notice inspection
Mental Health Commission	• Non-statutory, meet staff, discuss service • No exact date 2-3 weeks' notice & 1 day • Ensures important peoples' presence	• 1-2 days • Able to report on existing services, not 'showpiece'	• Publish Reports
HIQA Healthcare Services	• No exact date 6 weeks' notice and 4-6 hours' long • Assess compliance • Ensures important peoples' presence • Documentation easily available • Allows for a more in-depth inspection	• Assess compliance • 3 hours' long • Provides reassurance compliance with standards is the norm • Provide snapshot of standards • Limited in scope but prevent undue preparation therefore providing more real assessment of standard experienced by patients	• Publish Reports
Radiological Protections Institute of Ireland	• Verify compliance with regulations • 1 day - few weeks' notice & 2 hours to full day in length • Ensures important peoples' presence • Not always appropriate to disrupt in-going clinical practice • Certain procedures have to be planned well in advance	• Follow up on previous inspection outcomes/findings • Follow up on concern • Also useful for the regulated to know the Regulator carries out unannounced inspections • 2 hours to full day	• Most of the RPII's inspections are announced, but the inspection policy is constantly under review with changes in practice and the regulatory environment. RPII has an interest in our

			reports' findings
Department of Agriculture	• For new registrations • 1 week approx & 2/3 hours • Ensures important peoples' presence • Documentation easily available	• To detect non-compliances • 1 hour to a day • Operating practices cannot be visibly altered and non-compliances covered up	• Unannounced are far more effective in terms of detecting non-compliances or beaches but can be issues with non experienced personnel or lack of sufficient information available at the time of the inspection
HIQA – Adult Social Care	• New registration or 3 yearly renewal • 2 weeks' notice & 1 or 2 days' in length • Ensures important peoples' presence • Documentation easily available • Residents & family members can interact with inspectors • Increased efficiency = less visits	• 1 or 2 days • Ensures critical elements of care & support are in place 24/7 including staffing • Follow up on previous inspection findings & commitments • Ensures findings are based on the reality of the service • No scope for manipulation	• Publish reports
Environmental Protection Agency	• Typically 1-2 days' notice & half to full day • Ensures important peoples' presence • Documentation easily available • Meet own legislative required to conduct visits • Compliance with licence conditions & legislation • Check quality of environment	• Half to full day • Meet own legislative required to conduct visits • Inspector gets 'accurate picture of typical licence compliance • Public reassurance	• Publish Reports
National Employment Rights Agency	• Min 2 weeks' notice and inspection length depends on cooperation & compliance	• Approx. 30 mins long • Check who is working (children or non-national with no permit)	• Don't publish reports

	• Ensures important peoples' presence • Documentation easily available	• In conjunction with Revenue, Dept of Social Protection or Gardai • Breach of legislation can only be found through records inspection	
Health Service Executive	• Reasons vary	• Reasons vary	
International Regulators that perform a mixture of inspection types			
Name of Org	**Reasons/Benefits of Announced**	**Reasons/Benefits of Unannounced**	**Comments**
General Pharmaceutical Council	• No exact date 4-6 weeks' notice & 2-3 hours' long • No need for particular people present • Aim to replicate patients' experience • Expectation that standards are met every day & therefore no date should be given	• Aim to replicate patients' experience • For follow up on concerns/complaints • 2-3hours' long • Expectation that standards are met every day, not simply when inspector arrives • When investigating, it ensures obtaining the right information and accurate picture of daily operations	• Aiming to start publishing 'summary reports'
Pharmacy Regulation Authority, South Australia (PRASA)	• 'visits' are random across 3 years' • No exact date 6 months' notice & 2 hours' long • Assessing compliance • Level of remedial action may require re-visit • Notification lends itself to a spirit of cooperation, at least initially • Allows pharmacy opportunity for to implement measures to bring	• To confirm on-going adherence to standards and guidelines • Follow up on previous inspection outcomes/findings • Follow up on concern • Ensures 'actual' situation is seen • Ensures 'actual' commitment as opposed to suggested commitment	

	operations into alignment with necessary level before inspection • Removes adversarial context of visits		
Health Care Inspectorate, Netherlands	• No exact 1-6 weeks' notice & last 4 hours approx. • Determine compliance/risk assess • Ensures pharmacist presence • Increases efficiency • 'Cover-up' does not affect outcomes only if highly trained inspectors available	• More complaint/concern driven, led by public prosecution, inspectors assist & last 4 hours unless problems encountered • Also very short compliance inspections (1hour) by less qualified inspectors on tablets • History of non-compliance • Commitment of the Minister/Parliament to conduct mostly unannounced inspections	• 'semi-unannounced' visits – 24 hours' notice to enable important peoples' presence
Ontario College of Pharmacists	• New openings • No exact date Letter, 6 months' notice & 3-6 hours • Documentation easily available	• Same reasons as for announced • 3-6 hours • Specific appointments not given for logistic reasons	• Publish results
Tasmanian Pharmacy Authority	• For new registration or relocation of premises • 1 weeks' notice & 1 to 2 hours' long • Ensures important peoples' presence	• Once every 3 years approx. • Inspections are educative not punitive • Follow up on concerns/complaints • 1 to 2 hours' long • Where advance notice given, evidence could be destroyed • Follow up on previous inspection's findings/outcomes	• Encourage pharmacies to use 'self-audit' tool available through website (we have inspection checklist)
Pharmacy Council of New South Wales	• For new registration or relocation of premises **only** • Date & time agreed • 1 hour approx. • Ensures access to premises & staff	• Routine inspections at least once every 18 months • Follow up on previous inspection outcomes/findings • Follow up on concerns/complaints	

		• 30mins to 1hour – investigations take longer to conduct interviews, take documentations etc. • No need to give notice in relation to complaints matters	
Italian Medicines Agency AIFA, Italy			
Spanish Agency of Medicines and Medical Devices (AEMPS)	• 1 week approx. & 2-3 full days' long • Ensures important peoples' presence • Also for new registrations • Ensure no clash with other agencies' inspections	• Investigations into product quality problems or counterfeiting • 1-2 days' long • No scope for manipulation/ ensures evidence has not been manipulated	• Don't Publish

Regulators that perform **Announced Inspections only:**		
Name of Org	**Reasons/Benefits of Announced**	**Comments**
Veterinary Council	• 2-3 hours • Check compliance • Ensures important peoples' presence, certificate holder only person legally responsible for compliance • Documentation easily available	
Finnish Medicines Agency	• Routine hospital inspections 2 days long • Ensures important peoples' presence • Inspection will be shorter	
Regulators that perform **Unannounced Inspections only:**		
Name of Org	**Reasons/Benefits of Unannounced**	**Comments**
Alberta College of Pharmacists	• Monitoring & support • Address lean work flow management • 3-4 hours • Better use of inspector's resources • Pharmacies seen in natural state	• Given SMART goals (specific, measurable, achievable, realistic, timely) • 30 days to respond • Given ratings low to high
Pharmacy Registration Board of Western Australia	• Assess compliance with min standards • 1 hour long • Ensures premises compliant at all times & continuity of compliance	• Individual reports not printed, but summary of findings including in Board's Annual Report
Department of Health Social Services & Public Safety Northern Ireland	• For new registration inspections to ensure the premises meets standards • 'Routine' inspection of registered pharmacies to monitor and encourage compliance • 2-3 hours' long • Preference existed for unannounced • Give more realistic snapshot of how the pharmacy operates	• Don't publish reports

Appendix 4

Appendix 4

Certificates of Registration	% Unannounced	% Announced	Difference
Current certificate of registration for the RPB not available at the premises.	3%	1%	-2%
Current certificate of registration of the RPB not displayed such that it is legible by members of the public from the public pharmacy area.	29%	25%	-4%
Current certificate of registration for the Supervising Pharmacist not available at the premises.	4%	5%	1%
Current certificate of registration the Supervising Pharmacist not displayed such that it is legible by members of the public from the public pharmacy area.	33%	20%	-13%
Professional Cover & Duty Register			
No duty register for the current year	1%	0%	-1%
Not all entries for professional cover entered for the previous 2 months.	22%	5%	-17%
Entries not maintained contemporaneously.	17%	8%	-9%
Supervising Pharmacist does not provide professional cover in a regular capacity for a significant proportion of the opening hours.	10%	5%	-5%
Number of RPBs inspected which have a Pharmaceutical Assistant providing professional cover	28%	23%	-5%
Pharmaceutical Assistant providing professional cover in the temporary absence of the pharmacist, not in accordance with the terms of the Code of Practice Governing the Temporary Absence Clause of the Pharmacy Act 1890 (issued 1994)	49% (of 108 RPBs)	44% (of 9 RPBs)	-5%
SOPs			
No SOPs in place	4%	5%	1%
SOP's not specific to the operation of the pharmacy	18%	23%	5%
SOP's not approved by the Superintendent and/or Supervising pharmacist	28%	30%	2%
No evidence that staff have been trained on SOPs	40%	38%	-2%
Error & Incident Management			
No evidence that error/incident logs are being maintained	38%	23%	-15%
No records of resultant corrective actions implemented at the pharmacy	51%	48%	-3%
Premises & Layout			
Public part of the RPB not clean and/or professionally presented	4%	0%	-4%
Dispensary not clean and/or well maintained	20%	13%	-7%
Storeroom(s) not clean and/or well maintained	36%	35%	-1%
Toilets(s) not clean and/or well maintained	23%	20%	-3%
Patient Consultation Area			
No Patient Consultation Area in place	5%	3%	-2%
Area not private	14%	13%	-1%

Area not wheelchair accessible	21%	20%	-1%
Area not separate and/or designated	25%	23%	-2%
Area not accessible from the public pharmacy area	14%	15%	1%
Area not furnished	13%	10%	-3%
Storage of Medicines			
Fridge not a pharmaceutical grade fridge	15%	10%	-5%
Fridge not clean	8%	3%	-5%
Max/min fridge temperature not monitored and recorded on a daily basis	34%	33%	-1%
Max/min temperature in the dispensary not monitored and recorded on a daily basis	50%	53%	3%
Max/min temperature in storage areas not monitored and recorded on a daily basis	46%	43%	-3%
Expiry Dates			
No active expiry date management system in place	7%	8%	1%
No medicinal products waste bin in place	3%	0%	-3%
Traceability of Medicines			
Medicinal products which have been removed from their original packaging, not labelled appropriately	34%	20%	-14%
Controlled Drugs Safe			
No CD Safe	0.3%	0%	0%
CD safe not secured to a solid wall or floor in accordance with regulations	5%	3%	-2%
All CD2 & CD3's not being stored in the CD safe	8%	0%	-8%
Controlled Drugs Register			
No CD register	0%	0%	0%
Dates of supplies not entered	2%	0%	-2%
Patient names not entered	2%	0%	-2%
Patient addresses not entered	7%	15%	8%
Doctors names not entered	26%	28%	2%
Quantities supplied not entered	3%	5%	2%
Receipts from suppliers not entered	3%	3%	0%
Entries not made in a chronological sequence	14%	15%	1%
Running balances not maintained	10%	10%	0%
Errors not corrected by way of marginal or foot note	30%	18%	-12%
Controlled Drugs Balances			
The stock balance of three CD's in each pharmacy are checked against the actual quantity stored in the safe.			
Total CD Balances Incorrect	9%	7%	-2%

Prescription Register			
Prescription Register not being maintained	3%	5%	2%
3 dates are chosen from the previous 3 weeks and the prescription register is checked to see if these dates are available			
Total Prescription Registers not available for specific dates	10%	4%	-6%
Prescription register not certified by the pharmacist on a daily basis	22%	20%	-2%
Prescription Register not printed within 24 hours as required by legislation	21%	20%	-1%
Date the product is supplied is not recorded	3%	8%	5%
Name, quantity, (form), strength of the product not recorded	1%	3%	2%
Name of prescriber and address (where not known to the pharmacist) not recorded	26%	25%	-1%
Name and address of patient not recorded	3%	5%	2%
)ate on the prescription not recorded	53%	50%	-3%
Nature of Emergency Supply not recorded (when at the request of the patient)	57%	68%	11%
All required schemes not included in the prescription register	11%	18%	7%
Prescriptions Requested			
4 prescriptions are requested per pharmacy (These include prescriptions for controlled drugs and high tech medicines)			
Prescriptions not available	3%	4%	1%
Emergency supplies not in accordance with regulations	74%	100%	26%
Prescription not in date at the time of dispensing	8%	11%	3%
Prescription not written in accordance with the requirements of legislation	15%	16%	1%
Prescription does not match the entry in the Register	17%	27%	10%
Prescription not endorsed	30%	21%	-9%

Appendix 5

Current Rates of Domestic Travel and Subsistence

Mileage Rates

These are the rates for Mileage approved by the DOHC with effect from 25th March 2009

Official Mileage in a calendar year	Engine capacity Up to 1,200cc	Engine capacity Up to 1,201cc to 1,500cc	Engine capacity Up to 1,501cc and over
	Cent	Cent	Cent
Up to 4,000	64.54	76.94	97.95
4,001 and over	34.91	39.14	47.36

Kilometre Rates

These are the rates for Kilometre rates approved by the DOHC with effect from 25th March 2009

Official Mileage in a calendar year	Engine capacity Up to 1,200cc	Engine capacity Up to 1,201cc to 1,500cc	Engine capacity Up to 1,501cc and over
	Cent	Cent	Cent
Up to 4,000	40.11	47.82	60.88
4,001 and over	21.70	24.33	29.43

Subsistence Rates

These are the rates for Domestic Subsistence approved by the DOHC with effect from 25 March 2009. Overseas rates will be provided by the Finance Officer, where applicable.

The category of subsistence (class A or B) is based on the maximum of an individuals salary scale

Class A €55,780 and above
Class B €55,779 and below

Class of allowances	**Night Rate**	**Night Rate**	**Night Rate**	**Day Allowances**	**Day Allowances**
	Normal Rate[1]	Reduced Rate[2]	Detention Rate[3]	10 Hours or more	5 hours but less than 10 hours
	€	€	€	€	€
Class A	108.99	100.48	54.48	33.61	13.71
Class B	107.69	92.11	53.87	33.61	13.71

[1]Normal rate is payable for absence up to 14 nights. [2]This rate is payable for the next 14 nights. [3]This is the conference rate

Appendix 6

August 2013 Systems Inspection Authorised Officer 1

Unannounced					Distance	Overnights
	Pharmacy 1	Navan	Co. Meath	Day 1		
	Pharmacy 2	Navan	Co. Meath	Day 1		
	Pharmacy 3	Navan	Co. Meath	Day 1	106km	
	Pharmacy 4	Trim	Co. Meath	Day 2		
	Pharmacy 5	Trim	Co. Meath	Day 2		
	Pharmacy 6	Trim	Co. Meath	Day 2	48km	
	Pharmacy 7	Kells	Co. Meath	Day 3		
	Pharmacy 8	Navan	Co. Meath	Day 3		
	Pharmacy 9	Navan	Co. Meath	Day 3	134km	
Distance					**288km**	
Overnights						**0**

Announced					Distance	Overnights
	Pharmacy 1	Navan	Co. Meath	Day 1		
	Pharmacy 2	Navan	Co. Meath	Day 1	106km	
	Pharmacy 3	Navan	Co. Meath	Day 2		
	Pharmacy 4	Navan	Co. Meath	Day 2	106km	
	Pharmacy 5	Trim	Co. Meath	Day 3		
	Pharmacy 6	Trim	Co. Meath	Day 3	96km	
	Pharmacy 7	Navan	Co. Meath	Day 4		
	Pharmacy 8	Kells	Co. Meath	Day 4	134km	
	Pharmacy 9	Trim	Co. Meath	Day 5	96km	
Distance					**538km**	
Overnights						**0**

	Unannounced		Announced
Total	**9**		**9**
Days	**3**		**5**
Distance	**288km**		**538km**
Overnights	**0**		**0**

August 2013 Systems Inspections Authorised Officer 2

Unannounced					Distance	Overnights
	Pharmacy 1	Castlecomer	Co. Kilkenny	Day 1		
	Pharmacy 2	Castlecomer	Co. Kilkenny	Day 1		
	Pharmacy 3	Castlecomer	Co. Kilkenny	Day 1	204km	
	Pharmacy 4	Wicklow	Co. Wicklow	Day 2		
	Pharmacy 5	Wicklow	Co. Wicklow	Day 2		
	Pharmacy 6	Wicklow	Co. Wicklow	Day 2	95km	
	Pharmacy 7	Greystones	Co. Wicklow	Day 3		
	Pharmacy 8	Kilcoole	Co. Wicklow	Day 3	68km	
	Pharmacy 9	Bray	Co. Wicklow	Day 4	20km	
Distance					**387km**	
Overnights						**0**

Announced					Distance	Overnights
	Pharmacy 1	Wicklow	Co. Wicklow	Day 1		
	Pharmacy 2	Wicklow	Co. Wicklow	Day 1	95km	
	Pharmacy 3	Wicklow	Co. Wicklow	Day 2		
	Pharmacy 4	Kilcoole	Co. Wicklow	Day 2	95km	
	Pharmacy 5	Greystones	Co. Wicklow	Day 3		
	Pharmacy 6	Bray	Co. Wicklow	Day 3	52km	
	Pharmacy 7	Castlecomer	Co. Kilkenny	Day 4		
	Pharmacy 8	Castlecomer	Co. Kilkenny	Day 4	204km	
	Pharmacy 9	Castlecomer	Co. Kilkenny	Day 5	204km	
Distance					**650km**	
Overnights						**0**

	Unannounced		Announced
Total	**9**		**9**
Days	**4**		**5**
Distance	**387km**		**650km**
Overnights	**0**		**0**

August 2013 Systems Inspections Authorised Officer 3

Unannounced					Distance	Overnights
	Pharmacy 1	Knocknacarra	Co. Galway	Day 1		
	Pharmacy 2	Knocknacarra	Co. Galway	Day 1		
	Pharmacy 3	Knocknacarra	Co. Galway	Day 1	212km	1
	Pharmacy 4	Knocknacarra	Co. Galway	Day 2		
	Pharmacy 5	Salthill	Co. Galway	Day 2		
	Pharmacy 6	Westside	Co. Galway	Day 2	212km	
	Pharmacy 7	Carrick-on-Shannon	Co. Leitrim	Day 3		
	Pharmacy 8	Carrick-on-Shannon	Co. Leitrim	Day 3		
	Pharmacy 9	Carrick-on-Shannon	Co. Leitrim	Day 3	308km	
Distance					732km	
Overnights						1

Announced					Distance	Overnights
	Pharmacy 1	Knocknacarra	Co. Galway	Day 1		
	Pharmacy 2	Knocknacarra	Co. Galway	Day 1	212km	1
	Pharmacy 3	Knocknacarra	Co. Galway	Day 2		
	Pharmacy 4	Knocknacarra	Co. Galway	Day 2	212km	1
	Pharmacy 5	Salthill	Co. Galway	Day 3		
	Pharmacy 6	Westside	Co. Galway	Day 3		
	Pharmacy 7	Carrick-on-Shannon	Co. Leitrim	Day 4		
	Pharmacy 8	Carrick-on-Shannon	Co. Leitrim	Day 4	308km	1
	Pharmacy 9	Carrick-on-Shannon	Co. Leitrim	Day 5	308km	
Distance					1040km	
Overnights						3

	Unannounced		Announced
Total	9		9
Days	3		5
Distance	732km		1040km
Overnights	1		3

August 2013 Systems Inspections Authorised Officer 4

Unannounced					Distance	Overnights
	Pharamcy 1	Skibbereen	Co. Cork	Day 1		
	Pharmacy 2	Skibbereen	Co. Cork	Day 1		
	Pharmacy 3	Skibbereen	Co. Cork	Day 1	176km	
	Pharmacy 4	Cahirciveen	Co. Kerry	Day 2		
	Pharmacy 5	Cahirciveen	Co. Kerry	Day 2		
	Pharmacy 6	Waterville	Co. Kerry	Day 2	168km	1
	Pharmacy 7	Killarney	Co. Kerry	Day 3		
	Pharmacy 8	Killarney	Co. Kerry	Day 3		
	Pharmacy 9	Milltown	Co. Kerry	Day 3	156km	
Distance					500km	
Overnights						1

Announced						Distance	Overnights
	Pharmacy 1	Cahirciveen	Co. Kerry	Day 1			
	Pharmacy 2	Waterville	Co. Kerry	Day 1		168km	1
	Pharmacy 3	Cahirciveen	Co. Kerry	Day 2			
	Pharmacy 4	Milltown	Co. Kerry	Day 2		47km	1
	Pharmacy 5	Killarney	Co. Kerry	Day 3			
	Pharmacy 6	Killarney	Co. Kerry	Day 3		109km	
	Pharmacy 7	Skibbereen	Co. Cork	Day 4			
	Pharmacy 8	Skibbereen	Co. Cork	Day 4		88km	1
	Pharmacy 9	Skibbereen	Co. Cork	Day 5		88km	
Distance						500km	
Overnights							3

	Unannounced		Announced
Total	9		9
Days	3		5
Distance	500km		500km
Overnights	1		3

August 2013 Systems Inspections Authorised Officer 5

Unannounced					Distance	Overnights
	Pharmacy 1	Ballyjamesduff	Co. Cavan	Day 1		
	Pharmacy 2	Ballyjamesduff	Co. Cavan	Day 1	189km	
	Pharmacy 3	Kilbeggan	Co. Westmeath	Day 2		
	Pharmacy 4	Killucan	Co. Westmeath	Day 2	203km	
	Pharmacy 5	Cavan	Co. Cavan	Day 3		
	Pharmacy 6	Cavan	Co. Cavan	Day 3	224km	
	Pharmacy 7	Kingscourt	Co. Cavan	Day 4		
	Pharmacy 8	Virginia	Co. Cavan	Day 4		
	Pharmacy 9	Kingscourt	Co. Cavan	Day 4	207km	
Distance					**823km**	
Overnights						**0**

Announced					Distance	Overnights
	Pharmacy 1	Ballyjamesduff	Co. Cavan	Day 1		
	Pharmacy 2	Ballyjamesduff	Co. Cavan	Day 1	189km	
	Pharmacy 3	Kilbeggan	Co. Westmeath	Day 2		
	Pharmacy 4	Killucan	Co. Westmeath	Day 2	203km	
	Pharmacy 5	Cavan	Co. Cavan	Day 3		
	Pharmacy 6	Cavan	Co. Cavan	Day 3	224km	
	Pharmacy 7	Kingscourt	Co. Cavan	Day 4		
	Pharmacy 8	Kingscourt	Co. Cavan	Day 4	192km	
	Pharmacy 9	Virginia	Co. Cavan	Day 5	171km	
Distance					**979km**	
Overnights						**0**

	Unannounced		Annouced
Total	**9**		**9**
Days	**4**		**5**
Distance	**823km**		**979km**
Overnights	**0**		**0**

August 2013 Systems Inspections Comparison

	Unannounced	Announced	Difference
Inspections	45	45	0
Days	17	25	8
Distance	2730	3707	977
Overnights	2	6	4

Appendix 7

Private and Confidential
Dr Ambrose McLoughlin,
Secretary General,
Department of Health,
Hawkins House,
Hawkins Street,
Dublin 2

PSI
The Pharmaceutical Society of Ireland
AN RIALTÓIR CÓGAISÍOCHTA

23/12/2013

Re: Review of Unannounced Inspection System

Dear Dr McLoughlin, Ambrose,

The Pharmaceutical Society of Ireland (PSI) is an independent statutory body established by the Pharmacy Act 2007. One of the principal functions of the PSI is to regulate the profession of pharmacy in the State having regard to the need to protect, maintain and promote the health and safety of the public. In the discharge of this function, the PSI conducts inspections of pharmacies. Inspections are carried out in the following three circumstances:

i. Initial inspections for the purpose of registering a new pharmacy. These inspections are announced.
ii. Investigations for the purpose of examining suspected or alleged breaches of pharmacy and medicines legislation, Code of Conduct and PSI guidance. These are unannounced.
iii. Compliance inspections for the purpose of routinely assessing compliance with pharmacy and medicines legislation. These inspections are currently 'unannounced'.

The Council has requested its 'Inspection and Enforcement Committee' to review its policy in respect of the conduct of routine, not for cause compliance inspections (reference iii above), which to date has been operated on an 'unannounced' basis.

The basis of this proposal is that pharmacy owners would receive short advance notice of these inspections (typically one working day) to review staffing arrangements at the pharmacy on the day of the inspection to ensure that key personnel are present.

In view of the fact that this would constitute a significant change to current Council Policy in respect of the conduct of such inspections, it has been decided to seek the views of parties who may have a specific policy interest in this matter.

It should be noted that it is not intended that this proposed change would apply to initial inspections (e.g. for the purpose of registration of a new pharmacy) or to those that would be of an investigative nature.

The PSI's 'Inspection and Enforcement Committee" would, therefore, welcome views of your organisation on the concept of an 'announced' inspections format and would be grateful if it could receive any observations and comments that you may wish to make on the matter not later than the 20th January 2014.

Your assistance in this matter would be greatly appreciated.

Teach CCÉ, Sráid na bhFíníní, Baile Átha Cliath 2, Éire. PSI House, Fenian Street, Dublin 2, Ireland.
T. + 353 1 218 4000 F. + 353 1 283 7678 info@thepsi.ie www.thePSI.ie

Yours sincerely,

Marita Kinsella
Registrar, the Pharmaceutical Society of Ireland
cc Ms Lucia Crimin MPSI, Medicines, Controlled Drugs and Pharmacy Legislation Unit, Department of Health, Hawkins House, Hawkins Street, Dublin 2
Mr Paul Barron, Assistant Secretary, Department of Health, Hawkins House, Hawkins Street, Dublin 2

Appendix 8

An Roinn Sláinte
DEPARTMENT OF HEALTH

Oifig an Ard Rúnaí
Office of the
Secretary General

Ref No: QC2013/18064

Ms Marita Kinsella
Registrar
The Pharmaceutical Society of Ireland
PSI House
Fenian Street
Dublin 2

RECEIVED
08 JAN 2014

6th January 2014

Re: Review of Unannounced Inspection System.

Dear Ms Kinsella,

The Secretary General, Dr Ambrose McLoughlin has asked me to acknowledge receipt of your correspondence of 23rd December 2013 in the above regard and to let you know it is receiving attention.

Yours sincerely,

Derek Finnegan
Private Secretary to the Secretary General

RECEIVED
8 - JAN 2014

Cuirfear fáilte roimh chomhfhreagras i nGaeilge
An Roinn Sláinte / Department of Health
Teach Haicin Baile Átha Cliath 2
Hawkins House Dublin 2
Fón/Tel (01) 635 4361
Facs/Fax (01) 671 9884
R-phost/Email info@health.gov.ie
Suíomh Gréasáin/Web www.doh.ie

An Roinn Sláinte
DEPARTMENT OF HEALTH

RECEIVED
15 JAN 2014

14 January 2014

Ms Marita Kinsella
Registrar/CEO
Pharmaceutical Society of Ireland
PSI House
Fenian Street
Dublin 2

Re: Review of Unannounced Inspection System

Marita

Dear Ms Kinsella

I wish to refer to your letter of 23 December 2013 addressed to the Secretary General in which you sought the views of this Department to a proposal to change the system of routine pharmacy inspections from unannounced to announced inspections.

I wish to advise you that the Department would not be in favour of such a change to the current system of inspection. We believe that patient safety and public protection demand that a high level of standard is maintained at all times in pharmacies, as in other services. We believe that this is best regulated within the confines of unannounced inspections. Finally, we note that unannounced inspections are standard practice in other service areas and we are of the view that this should continue to be replicated in the pharmacy sector.

I trust that this clarifies the Department's position.

Yours sincerely

Paul Barron
Assistant Secretary

Tús Áite do Shábháilteacht Othar
Patient Safety First

Cuirfear fáilte roimh chomhfhreagras i nGaeilge
An Roinn Sláinte / Department of Health
Teach Hawkins Baile Átha Cliath 2 / Hawkins House Dublin 2
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Suíomh Gréasáin/Web www.doh.ie

IRISH
PHARMACY
UNION

The voice of community pharmacy

RECEIVED
06 JAN 2014

Ms Marita Kinsella
Registrar and CEO
Pharmaceutical Society of Ireland
PSI House
Fenian Street
Dublin 2

03 January 2014

Dear Marita,

Thank you for your letter dated 23 December 2013 regarding the review of the PSI's policy in respect of the unannounced nature of routine, not for cause, compliance inspections of pharmacies. The Irish Pharmacy Union welcomes and strongly supports the proposal that pharmacy owners would receive advance notice of these inspections; indeed, it is something we have long sought.

The primary purpose of any inspection regime should be to maintain and raise standards in the sector, rather than simply to identify and punish non-compliance. Moving to a system of announced inspections facilitates this.

Undergoing a PSI inspection is a stressful experience for any pharmacist and is a significant distraction from their primary professional responsibility to their patients and the public. The current system of unannounced inspections means that, in many cases, there is a risk to patient safety associated with a busy pharmacist's attention being taken away from their professional duties as they attempt to produce various documents and policies following the unexpected appearance of the PSI inspector.

However, your suggestion that a single day's notice would be given falls short of what is reasonably required where staff rosters and other arrangements may need to be changed by Pharmacy Owners and/or Supervising Pharmacists, in order to cope with the additional workload involved in assisting the authorised officers' inspection of the pharmacy. One week's notice, sent by post or by email to both the Pharmacy Owner and to the Supervising Pharmacist, would be more appropriate to allow them sufficient time to reorganise the pharmacy rota to ensure adequate attendance of the relevant staff on the day of inspection, and even to be present themselves if they wished. It would also allow the pharmacist time to review their documentation in order to ensure all appropriate relevant registers, records and other paperwork were available and easily accessible, rather than having to dig the various documents out on the day.

One week's notice would not be sufficient to make a non-compliant pharmacy compliant, so the intent of the inspection regime would not be undermined; however, it would help a pharmacy which is well run demonstrate this fact in a less fraught and pressurised manner than is currently the case.

IRISH PHARMACY UNION
Butterfield House Butterfield Avenue Rathfarnham Dublin 14
T +353 1 493 6401 F +353 1 493 6407 E info@ipu.ie W www.ipu.ie

We welcome the opportunity to comment on this very welcome proposal and are available to discuss the matter further.

Yours sincerely,

Darragh J. O'Loughlin
Secretary General

RECEIVED

15 JAN 2014

Irish Patients' Association

Ms Martina Kinsella.
Registrar Pharmaceutical Society of Ireland
PSI House
Fenian St
Dublin 2
Jan 9th 2014

Dear Martina

Re Consultation re announced / unannounced routine Audits

Firstly may I congratulate you and wish you every success in your new role and thank you for this opportunity to respond to the council's review of its routine inspection process.

- We are not in favour of having announced visits for routine inspections. The reason for this is that there is a perception that announced visits weakens the Regulatory process insofar as an opportunity can be created perceived or not that a facility gets valuable time to better presents their position.
- If this proposal is also driven to ensure that the inspectors time is not wasted by ensuring that the appropriate competent personnel are available for an audit – surly if an unannounced visit is conducted and an appropriate competent person is not available then this must say something about the enterprises management.
- If the competent person is not available at time of a visit then the council could consider a fine to cover its costs.
- If advanced notice is to be allowed as standard process then what is to be done if the person they need to see is not available within the 24hrs notice. What is to be done if the person goes on leave?
- Finally, there may be a case for announced visits with supporting criteria eg Clear previous Audit etc, if this is reasonable then governance of this option must be demonstrated to ensure that it does not become the norm to suit business need and not Regulatory Governance

Yours Sincerely

Stephen MCMAHON
Chairman

Patient Safety First

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PATIENT FOCUS

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Ms Marita Kinsella

Registrar

The Pharmaceutical Society of Ireland

PSI House

Fenian St

Dublin 2

06.01.2014

Re: Review of Unannounced Inspection System

Dear Ms Kinsella

Thank you for your letter of 23.12.13 concerning the review of unannounced inspections in cases of routine compliance inspections of pharmacies and proposed changes in relation to this matter.

It is Patient Focus strong view that unannounced inspections provide safeguards for patients and the general public in a way that announced inspections cannot do. They are more reassuring to customers and patients in relation to quality and safety. An appropriate solution may the use of both announced inspections and unannounced inspections. The lack of availability of specific owners or staff which can arise with unannounced inspections can be overcome by employing both types of inspections.

It is important to note that the change of practice envisaged by your letter would weaken the ability of the Pharmaceutical Society of Ireland to provide the necessary safeguards required to protect patients and indeed the general public. It could also lead to a lessening of the trust now enjoyed by the PSI in the performance of their compliance functions and indeed in the perception of the accountability of pharmacists. Patient Focus believes this would be very unfortunate indeed.

I hope this is of use to you with your important deliberations.

Yours sincerely

Sheila OConnor

RECEIVED
8 - JAN 2014

Health Information and Quality Authority
An tÚdarás Um Fhaisnéis agus Cáilfocht Sláinte

Marita Kinsella
Registrar
Pharmaceutical Society of Ireland
PSI House
Fenian Street
Dublin 2

Ref: PQ/FY/MK/160114

16 January 2014

Dear Marita,

Thank you for your letter to Tracey Cooper dated 23 December 2014 in which you seek HIQA's views on the introduction of a system of inspection that utilises both announced and unannounced inspections within pharmaceutical premises.

I note the three circumstances listed in your inspection regime and the current methods used, which to some extent mirror the mechanisms traditionally used by ourselves and other regulators within health and social care sector.

By way of background I would point out that we have started to utilise announced inspections in our ongoing post registration inspection work as we have recently attempted to place increasing emphasis on the objective of driving improvement within health and social care services as well as monitoring compliance with standards and regulations. The use of announced inspection in some services is also aimed at enabling greater access to information on governance and safety systems that may not be available on the basis of unannounced activity.

Interestingly there is not a great deal of research into the area of the benefits or otherwise of announced versus unannounced inspection but we are part of a wider European network of health and social care regulators, The European Network For Supervisory Organisations (EPSO) where there was a recent study presented on comparative outcomes from both methods. The basic conclusion was that there was little difference in the detection of non compliance factors in using both methods and the ensuing discussion at the EPSO meeting was clearly focused on the public and political focus and emphasis on unannounced methods at being the most effective. The following link will bring you to the abstract for the Dutch study:

http://www.healthpolicyjrnl.com/article/S0168-8510(13)00126-7/abstracthttp://www.healthpolicyjrnl.com/article/S0168-8510(13)00126-7/abstract

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By way of interest, the autumn meeting (2014) of the network will be jointly hosted in Dublin by ourselves and the Mental Health Commission, you might be interested in joining the discussions that will focus on regulation and related topics.

More specifically you ask about the introduction of an announced element in inspection aimed at investigation or examination of alleged or suspected breaches of pharmacy or medicines legislation, code of conduct and PSI guidance. Your letter does not outline the specific rationale or motivation for the proposed change but it would appear that a universal application of an announced element in what is a key service user/ patient safety issue might damage public confidence in your existing system. The proposal to move to a 24 hour notice period for issues such as assessment of staffing levels might be viewed as introducing an opportunity to enable the provider to introduce a "temporary fix" to enable an assessment of compliance. Such a system would need to be underpinned by a very robust system of ongoing risk assessment informed by intelligence on how an operator is conducting their business, enabling the use of such information as evidence in any enforcement or professional conduct proceedings. In this instance I would suggest that any policy in respect of change should not include the universal application of announced inspection.

Whilst we would use announced inspections in the course of an investigation of circumstances where there is concern on service user/patient safety and welfare, we would also continue to apply an unannounced regime where we have concerns or where we believe there is emergent or actual risk.

I hope the above view is of some use to the committee. Should you require any further clarification on any of the above, please do not hesitate to contact me.

I would also like to offer you or any of your inspection staff to meet with some of our staff who have recently introduced our new methodological framework, being used across all of our regulatory functions, the Authority Monitoring Approach (AMA). The approach is aimed at ensuring increased consistency of our application of standards and regulations across services through common assessment and judgement frameworks.

Yours sincerely,

Phelim Quinn
Director of Regulation

cc. Tracey Cooper, Chief Executive, Health Information and Quality Authority

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MHC
Coimisiún Meabhair-Shláinte | Mental Health Commission

Ms. Marita Kinsella
Registrar, the Pharmaceutical Society of Ireland
PSI House
Fenian Street
Dublin 2

10th January 2014

RECEIVED
14 JAN 2014

Re: Review of Unannounced Inspection System

Dear Ms. Kinsella,

I acknowledge receipt of your correspondence of 23rd December 2013 requesting views on behalf of your Inspection and Enforcement Committee in relation to routine compliance inspections.

As you are aware, unannounced inspections are perceived as best practice and generally provide a better insight than announced inspections (from a societal and political perspective). From a practical perspective, the announcement of an inspection can be useful, in that files, other documents and relevant personnel are readily available.

A combination of announced and unannounced inspections may provide a good overall view. An option which would provide for an unannounced inspection at a point in time following an announced inspection, if deemed appropriate, may also be worthy of consideration.

Should you wish to revert, please do not hesitate to do so.

Yours sincerely,

Patricia Gilheaney
Chief Executive